FORM PTO-1390 (REV. 12-2001) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U S APPLICATION NO (If known, see 37 CFR 1.5
DFS-148-A	10/089817

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/09715	05 October 2000	06 October 1999

TITLE OF INVENTION CATHETER FOR CARRYING OUT THE COMBINED EXAMINATION OF THE LEFT VENTRICLE AND OF THE RIGHT AND LEFT CORONARY ARTERIES

APPLICANT(S) FOR DO/EO/US
Thomas Wolffgram and Axel Krieter

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [X] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [ ] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Unsigned
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [ ] Other items or information:

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
Unknown 10/089817	PCT/EP00/09715	DFS-148-A

21. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [X] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	21 - 20 =	1	x **$18.00**	$ 18
Independent claims	- 3 =		x **$84.00**	$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$280.00**	$

TOTAL OF ABOVE CALCULATIONS =	$ 1038
[X] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. +	$ 519
SUBTOTAL =	$ 519
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [X] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).	$ 130
TOTAL NATIONAL FEE =	$ 649
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$ 0
TOTAL FEES ENCLOSED =	$ 649
	Amount to be refunded: $
	charged: $

a. [X] A check in the amount of $ 649.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 25-0115. A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

William M. Hanlon, Jr.
NAME

28422
REGISTRATION NUMBER

Our Reference: DFS-148-A PATENT #6/a

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Thomas Wolffgram & Axel Krieter
Serial Number:	10/089,817
Filing Date:	April 4, 2002
Examiner/Art Group Unit:	Unknown/Unknown
Title:	CATHETER FOR CARRYING OUT THE COMBINED EXAMINATION OF THE LEFT VENTRICAL AND OF THE RIGHT AND LEFT CORONARY ARTERIES

PRELIMINARY AMENDMENT

Box Non-Fee Amendment
Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

If any charges or fees must be paid in connection with the following communication, they may be paid out of our Deposit Account No. 25-0115.

Prior to initial examination, please amend the above-identified patent application as indicated below.

In the specification:

An abstract has been added.

In the claims:

Claims 1-21 are cancelled.

Claims 22-63 are added.

REMARKS

After entry of this amendment, claims 1-21 have been cancelled without prejudice. Claims 22-63 have been added in this amendment.

A handwritten, corrected copy of the specification is enclosed showing the changes which have been made to the specification as required by Section 608.01(Q) and 714.20(1) of the Manual of Patent Examining Procedure. The Substitute Specification filed herewith has been amended to utilize idiomatic English, correct minor typographical and grammatical errors and to conform the application to current United States patent practice. The Substitute Specification includes no new subject matter; but does include the same changes handwritten in red in the attached, corrected, original specification. Entry of the Substitute Specification is respectfully requested.

It is submitted that this Amendment has antecedent basis in the application as originally filed, including the specification, claims and drawings, and that this Amendment does not add any new subject matter to the application. Consideration of the application as amended is requested.

Respectfully submitted,

YOUNG, BASILE, HANLON, MacFARLANE, WOOD & HELMHOLDT, P.C.

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Dated: June 5, 2002
WMH/jao

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

After the claims, start a new page and insert–

ABSTRACT

A multi-lumen catheter and a device for perfusing X-ray contrast media or pharmacologically effective substances with which X-ray contrast media or pharmacologically effective substances can be introduced into the left cardiac chamber, the coronary arteries and into other exits of the aorta without changing the catheter. This results in a reduction of the stress to which the patient is subjected, in particular during angiographic examinations, by distinctly reducing the duration of the examination, the exposure to radiation, the risk of examination-related disturbances of cardiac rhythm, and cardiac infarctions as well as the risk of infection.

In the claims:

Cancel claims 1-21 and substitute therefore the following new claims:

22. (New) A multi-lumen catheter having an expandable balloon, where the balloon is connected to a first lumen, and having a second lumen, where the second lumen has at least one outlet, the at least one outlet of the second lumen is located between the balloon and a distal end of the catheter, characterized in that the catheter is used for at least one of the angiography of coronary arteries, aortocoronary bypasses and other exits of the aorta and its branches.

23. (New) The catheter in accordance with claim 22, wherein the catheter has a third lumen having at least one outlet, and wherein the at least one outlet of the third lumen is located between the at least one outlet and the distal end of the catheter.

24. (New) The apparatus in accordance with claim 22, wherein the catheter has a third lumen connecting to one of a second contrast medium pump and syringe having at least one outlet, and wherein the at least one outlet of the third lumen is located between at least one outlet of the second lumen and the distal end of the catheter.

25. (New) The catheter in accordance with claim 22, wherein the at least one outlet of the second lumen is located at a distance of 0 mm to 60 mm from the balloon.

26. (New) The catheter in accordance with claim 22, wherein the at least one outlet of the third lumen is located at a distance of 0 mm to 50 mm from the distal end of the catheter.

27. (New) The catheter in accordance with claim 22, wherein the at least one outlet of the second lumen is located at a distance of 0 mm to 60 mm from the distal end of het catheter.

28. (New) The catheter of claim 27, wherein the distance between the at least one outlet of the second lumen and the at least one outlet of the third lumen is 60mm to 140mm.

29. (New) The catheter in accordance with claim 22, wherein the balloon is filled with one of gas and fluid.

30. (New) The catheter in accordance with claim 22, wherein the balloon is conical in an expanded state, and wherein the diameter of the balloon increases with increasing distance from the distal end of the catheter.

31. (New) The catheter or apparatus in accordance with claim 22, wherein the catheter has X-ray reflective markings in the area of the at least one outlet of the third lumen and the at least one outlet of the second lumen.

32. (New) The catheter in accordance with claim 22, wherein the catheter is bent at its distal end in the shape of one of a pigtail, a circle and a spiral.

33. (New) An apparatus for perfusing a contrast medium having a multi-lumen catheter with an expandable balloon, where the balloon is connected to a balloon pump by means of a first lumen having a second lumen, where the second lumen has at least one outlet which is connected through the second lumen to one of a first contrast medium pump and a syringe, characterized in that the at least one outlet of the second lumen is located between the balloon and the distal end of the catheter.

34. (New) The apparatus in accordance with claim 33, wherein the catheter has a third lumen connecting to one of a second contrast medium pump and syringe having at least one outlet, and wherein the at least one outlet of the third lumen is located between at least one outlet of the second lumen and the distal end of the catheter.

35. (New) The apparatus in accordance with claim 33, wherein the at least one outlet of the second lumen is located at a distance of 0 mm to 60 mm from the balloon.

36. (New) The apparatus in accordance with claim 33, wherein the at least one outlet of the third lumen is located at a distance of 0 mm to 50 mm from the distal end of the catheter.

37. (New) The apparatus in accordance with claim 33, wherein the at least one outlet of the second lumen is located at a distance of 0 mm to 60 mm from the distal end of het catheter.

38. (New) The apparatus in accordance with claim 37, wherein the at least one outlet of the second lumen is located at a distance of 0 mm to 60 mm from the distal end of the catheter.

39. (New) The apparatus in accordance with claim 33, wherein the balloon is filled with one of gas and fluid.

40. (New) The apparatus in accordance with claim 33, wherein the distance between the at least one outlet of the second lumen and the at least one outlet of the third lumen is approximately the length of the left ventricle.

41. (New) The apparatus in accordance with claim 33, wherein the balloon is conical in an expanded state, and wherein the diameter of the balloon increases with increasing distance from the distal end of the catheter.

42. (New) The apparatus in accordance with claim 22, wherein the balloon is filled with one of gas and fluid.

43. (New) The apparatus in accordance with claim 33, wherein the catheter has X-ray reflective markings in the area of at least one of the at least one outlet of the third lumen and the at least one outlet of the second lumen.

44. (New) The apparatus in accordance with claim 33, wherein the catheter is bent at its distal end in the shape of one of a pigtail, a circle and a spiral.

45. (New) The apparatus in accordance with claim 33, wherein the balloon pump is controlled by EKG equipment.

46. (New) The apparatus in accordance with claim 33, wherein the balloon pump inflates the balloon during particular heart phases, including at least one of systole and diastole, and an independently selected phase range of the heart cycle, and continuously over several heart cycles.

47. (New) The apparatus in accordance with claim 33, wherein the balloon pump empties the balloon during particular heart phases, including at least one of systole, diastole, an independently selected phase range of the heart cycle, and continuously over several heart cycles.

48. (New) The apparatus in accordance with one of the claim 33, wherein the first contrast medium pump can be controlled from EKG equipment.

49. (New) The apparatus in accordance with claim 33, wherein the first contrast medium pump conveys contrast medium into the catheter during particular heart phases, including at least one of systole, diastole, an independently selected phase range of the heart cycle, and continuously over several heart cycles.

50. (New) The apparatus in accordance with claim 33, wherein the second contrast medium pump is controlled by EKG equipment.

51. (New) The apparatus in accordance with claim 33, wherein the second contrast medium pump conveys contrast medium into the catheter during particular heart phases, including at least one of systole, diastole, an independently selected phase range of the heart cycle, and continuously over several heart cycles.

52. (New) The apparatus in accordance with claim 33, wherein the pressure in at least one of the environment of the balloon and the outlets can be measured through at least one of the first lumen, the second lumen and the third lumen.

53. (New) The apparatus in accordance with claim 33, wherein pharmacologically effective substances are injected through the second lumen and the third lumen.

54. (New) A method for perfusing a contrast medium through a multi-lumen catheter with an expandable balloon comprising the steps of:

connecting the balloon to a balloon pump by means of a first lumen;

providing a second lumen having at least one outlet, the first lumen connecting the first lumen through the second lumen to one of a first contrast pump and a syringe; and

locating at least one outlet of the second lumen between the balloon and a distal end of the catheter.

55. (New) The method of claim 54 further comprising the steps of:

providing the catheter with a third lumen;

connecting the third lumen to one of a second contrast medium pump and a syringe having at least one outlet; and

locating at least one outlet of the third lumen between the at least one outlet of the second lumen and the distal end of the catheter.

56. (New) The method in accordance with claim 54 further comprising the step of:

inflating the balloon during particular heart phases, including during at least one of systole or diastole, or during an independently selected phase range of the heart cycle, or continuously over several heart cycles.

57. (New) The method in accordance with claim 54 further comprising the step of:

emptying the balloon during particular heart phases including during at least one of systole or diastole, or during an independently selected phase range of the heart cycle, or continuously over several heart cycles.

58. (New) The method in accordance with claim 54 further comprising the step of:

controlling the first contrast medium pump by EKG equipment.

59. (New) The method in accordance with claim 54 further comprising the step of:

using the first contrast medium pump to convey contrast medium into the catheter during particular heart phases including during at least one of systole or diastole, or during an independently selected phase range of the heart cycle, or continuously over several heart cycles.

60. (New) The method in accordance with claim 54 further comprising the step of:

controlling the second contrast medium pump by EKG equipment.

61. (New) The method in accordance with claim 54 further comprising the step of:

using the second contrast medium pump to convey contrast medium into the catheter during particular heart phases including during at least one of systole or diastole, or during an independently selected phase range of the heart cycle, or continuously over several heart cycles.

62. (New) The method in accordance with claim 54 further comprising the step of :

measuring the pressure of at least one of the environment of the balloon and the outlets through at least one of the first lumen, the second lumen and the third lumen.

63. (New) The method in accordance with claim 54 further comprising the step of :

injecting pharmacologically effective substances through at least one of the second lumen and a third lumen.

SUBSTITUTE SPECIFICATION

Our Reference: DFS-148-A PATENT

CATHETER FOR CARRYING OUT THE COMBINED EXAMINATION OF THE LEFT VENTRICLE AND OF THE RIGHT AND LEFT CORONARY ARTERIES

BACKGROUND

[0001] The invention takes as its point of departure a multi-lumen catheter having an inflatable balloon, where the balloon connects to a first lumen, and having a second lumen, where the second lumen has at least one outlet, and a device for perfusing a contrast medium with a multi-lumen catheter having an inflatable balloon, where the balloon connects over a first lumen with a balloon pump, and having a second lumen where the second lumen has at least one outlet which connects over the second lumen to a first contrast medium pump.

[0002] In order to be able to perform an X-ray examination of the left ventricle and the left and right coronary arteries, or respectively other aortic orifices or aortocoronary bypasses, a radiopaque X-ray substance is pumped by means of a catheter into the area of the heart to be examined. Using an X-ray camera, the volume, or the change in volume respectively, of the left cardiac chamber, hereafter called the left ventricle, and the blood circulation in the coronary arteries can be shown on an X-ray screen.

[0003] Examinations of this kind are used for the combined sequential angiographic presentation of the left cardiac chamber and coronary arteries if there is a clinical suspicion of coronary heart disease, diseases of the myocardium of the left cardiac chamber (e.g. condition following myocardial infarction with reduced contractility of the myocardium), vitiation and similar conditions.

[0004] At the present time, several catheters are used in sequence when these examinations are performed, when one catheter is first inserted into the arteria femoralis or the arteria brachialis through an entry in the groin and then advanced into the left ventricle. Through a passage – henceforth referred to as a lumen – in the catheter, having an opening at the tip of the catheter, contrast medium is injected

staff must remain standing at the examination table during the X-ray examinations, whereby they are exposed to X-ray radiation. The inventive catheter not only shortens the overall examination but possibly also allows stepping away briefly from the examination table during the time of the X-ray examinations.

[0009] The specially shaped catheters for examining the coronary arteries in the prior art have to be introduced into the coronary arteries and there, particularly with arteriosclerotic plaques close to the arterial trunk , they can result in a rupture and, in extreme cases, to acute infarction. Moreover, the danger of arterial dissection and a relative ischemia exists, caused by the highly concentrated, oxygen-poor contrast medium. With unfavorable anatomical conditions or variants thereof, or with a condition following an aortocoronary bypass operation it may also be necessary to introduce more than two catheters to examine the coronary arteries.

[0010] In order to obtain an improved image of the area of the heart being examined, it is proposed in WO 91/08791 that the areas of the heart not being examined be segregated by suitable blocking means from the area of the heart being examined. As a result, the concentration of contrast medium in the area of the heart to be examined can be increased and thus improve the image of the area of the heart to be examined. One possible means of segregating one area of the heart from another area is an inflatable balloon, which is located, for example, at the tip of the catheter and can be dilated by a pump connected by means of a lumen in the catheter to the balloon. If a catheter of this kind with its tip is introduced into a coronary artery and the balloon is inflated, almost no blood continues to flow out of the aortic bulb into the blocked off coronary artery. This increases the blood circulation in the other coronary artery or the concentration of the contrast medium injected into the aortic bulb in the other coronary artery. The image of a coronary artery on the screen is somewhat improved by this cardiac catheter; however, the basic problem remains that in order to examine the left ventricle and both coronary arteries at least three catheters have to be inserted. Furthermore, the blocking off, even if only for a short time, of one coronary artery results in a temporary undersupply of the blocked off coronary artery and the resulting undesirable potential consequences for the patient. As with conventional single-lumen catheters for showing individual coronary

the outflow of blood and contrast medium into the aorta ascendens. For this, the balloon is positioned immediately above the aortic bulb and the balloon is expanded in synchronization with the injection of the contrast medium.

[0019] Supplemental to the invention it is envisioned that the outlet, or outlets, of the third lumen are located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 50 mm from the distal end of the catheter, so that contrast medium can be injected into the left ventricle for viewing.

[0020] One supplement to the invention provides for the outlet, or outlets, of the second lumen to be located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 60 mm from the distal end of the catheter, so that the catheter is pushed forward into the left ventricle to examine the left ventricle and then the contrast medium can be injected in the interior of the left ventricle below the aortic valve.

[0021] In another embodiment of the invention, it is envisioned that the distance between the outlet(s) of the second lumen and the outlet(s) of the third lumen is approximately equal to the inside longitudinal diameter of the left ventricle and is specifically 60 mm to 140 mm, so that both the left ventricle and also the coronary arteries can be filled with contrast medium with the catheter in one position.

[0022] In another embodiment of the invention, the balloon can be filled with gas or fluid, so that an economical and unproblematic medium is available to fill the balloon.

[0023] Another embodiment of the invention provides for the balloon to be conical in its expanded state and for the diameter of the balloon to increase with increasing distance from the distal end of the catheter, so that basically it is also possible to use the balloon for a controlled extended inflation of about 4 to 5 seconds duration. For this the lumen of the aorta is not reduced completely but up to about two-thirds of the diameter previously determined by echocardiography. This ensures that adequate residual blood circulation is preserved in all peripheral and specifically cranial arteries.

[0024] Another variation of the invention envisions that the catheter in the area of the outlets of the third lumen and/or in the area of the outlets of the second lumen

for the third lumen supply contrast medium to the catheter during specific phases of cardiac activity, specifically diastolic, or continuously over several heart cycles (heartbeats), so that with the economical use of contrast medium in the areas of the heart to be examined a highest possible local concentration of contrast medium is available, and thus a good representation of the areas of the heart to be examined, showing the blood circulation conditions in the heart, is possible on the X-ray screen.

[0030] In a variation of the invention, it is envisioned that through first lumen, second lumen and/or third lumen the pressure in the environment of the balloon and/or the outlet is measurable, so that a measurement of the pressures in left ventricle and aortic bulb, which should precede a coronary angiography, is possible without additional stress for the patient and almost without prolonging the overall duration of the examination.

[0031] In a further embodiment of the invention, pharmacologically effective substances, specifically for thrombolytic therapy following an acute cardiac infarction, are injected, so that the pharmacologically effective substances attain improved concentration, compared with systemic administration.

BRIEF DESCRIPTION OF THE DRAWING

[0032] Additional advantages and advantageous embodiments of the invention can be found in the following drawing, the description and the claims. In the drawing:

[0033] Figures 1a-1d show a first embodiment of an inventive catheter in various cross sections;

[0034] Figures 2a-2c shows a second embodiment of an inventive catheter in various cross sections;

[0035] Figures 3a and 3b show a schematic representation of the heart with an inventive catheter; and

[0036] Figure 4 shows: a heart with an inventive apparatus.

DETAILED DESCRIPTION

[0037] Figure 1a shows a first embodiment of an inventive catheter 1 having three lumina. Figure 1b shows the catheter 1 along the section line I-I. In this representation, a first lumen 3, a second lumen 5 and a third lumen 7 can be seen. A

filled with contrast medium without having to change the position of the catheter 1 with respect to the heart.

[0040] Figures 2a-2c show a second embodiment of an inventive catheter 1. The same components are given the same reference numbers. Reference is made to the description of Figures 1a-1d with respect to an explanation thereof.

[0041] The fundamental difference compared with the first embodiment is that there is no third lumen. For this reason catheter 1 can be configured with a smaller diameter, which makes its introduction through a shunt in the groin easier, or respectively makes a smaller shunt possible. Furthermore, manufacturing costs are reduced. An additional difference is that balloon 9 is located in the immediate proximity of the distal end 13 of the catheter 1. In order to examine the left ventricle, the catheter is pushed through the aorta into the left ventricle until the distal end 13 of the catheter lies against the side of the left ventricle opposite the aortic valves or is in the immediate proximity of this side. In this position the balloon is deflated, that is, it is lying against catheter 1 and has no function in this position. The examination of the left ventricle is undertaken in the usual way. When this examination is concluded the catheter is retracted somewhat, just far enough until the outlets 15 are in the area of the aortic bulb or coronary arteries respectively. In this position the balloon 9 is positioned in the aorta and can increase the concentration of contrast medium in the coronary arteries, as described above. It is much simpler to contrive to move the catheter 1 during an examination than to change a catheter and furthermore it can be carried out more quickly, so that examination time and stress on the patient are reduced.

[0042] Figure 3a shows a heart 23 in systole with the inventive catheter 1. The catheter 1 extends into the left ventricle 24, while the balloon 9 is positioned above the aortic bulb 25. During systole the balloon 9 is deflated, that is, it is lying basically flat against the catheter 1 and thus causes only minor resistance to the outflowing blood in the aorta 27, indicated by arrows 30. Also indicated is a coronary stenosis 28, which results in the tissue 29 that lies behind the coronary stenosis 28 in the direction of flow being poorly supplied with blood. The discovery

of such coronary stenoses shall be made easier with the assistance of the inventive catheter 1 by delivering a contrast medium (not shown) into the coronary arteries 31.

[0043] This procedure is depicted in Figure 3b. It shows the heart during diastole, that is, the left ventricle 24 is increasing its volume and thus wants to draw blood back out of the aorta 27. This is prevented by the aortic valves 33 which are closed because of the pressure differential between left ventricle 24 and aorta 27. The incipient backflow of blood out of the aorta 27 in the direction of the left ventricle results in blood, or contrast medium respectively, which is leaving the outlets 15 of the catheter (see Figure 1 and Figure 3), flowing into the coronary arteries. In Figure 3b, the contrast medium is suggested by showing the coronary arteries 31 filled with contrast medium in black. The balloon 9 is inflated during diastole so that its volume is enlarged and it thus supports, or reinforces, the return flow of blood, or contrast medium respectively, from the area of the aortic bulb as far as the balloon 9 into the coronary arteries. The expansion of the balloon is indicated in Figure 3b by arrows. As a result, and because the drainage of contrast medium through the aorta is prevented, the concentration of contrast medium in the area of the aortic bulb and the coronary arteries is increased compared with traditional cardiac catheters, without degrading the oxygen supply to the coronary arteries.

[0044] When the left ventricle is to be examined, the balloon is deflated and contrast medium is pumped out of the outlets 21 (see Figure 1) into the left ventricle 24. From Figure 3 it is clear that left ventricle 24 as well as both coronary arteries 31 can be examined without the necessity of changing the position of catheter 1. This simplifies the examination, and the time required is drastically reduced by restricting X-ray photographs for checking the position to a minimum. Consequently, the stress from X-rays for patient, physician and attending staff is also reduced. At the same time the images of the areas of the heart being examined 23 are improved.

[0045] Figure 4 shows a heart 23 with catheter 1 inserted and the other components of an inventive apparatus for perfusing contrast media. The first lumen 3 of catheter 1 is connected to a balloon pump 35. The second lumen 5 is connected to a first contrast medium pump 37, while the third lumen 7 is connected to a second contrast medium pump 39. The balloon pump 35 and first and second contrast

medium pumps 37 and 39 are controlled from EKG equipment 41, which is hooked up to the patient 43, who is shown in highly simplified form. As the result of this arrangement, the balloon 9 is deflated during systole and inflated during diastole. Additionally the moment for perfusing the contrast medium can be selected.

[0046] The contrast medium in the heart 23 can be shown on a screen 47 by means of an X-ray camera 45. The embodiment of the catheter 1 shown in Figure 4 has a so-called pigtail, meaning that its distal end 13 is curved in the shape of a spiral, so that damage to the heart wall or unintentional penetration of one of the coronary arteries 32 is prevented.

[0047] All the features presented in the description, the following claims and the drawing can be essential to the invention both individually as well as in any combination with each other.

located in the proximity of the balloon (9), specifically at a distance of 0 mm to 60 mm from the balloon (9).

6. Catheter or apparatus in accordance with one of the preceding claims, wherein the outlet (21), or the outlets (21), of the third lumen (7) are located in the proximity of the distal end (13) of the catheter (1) specifically at a distance of 0 mm to 50 mm from the distal end of the catheter (1).

7. Catheter or apparatus in accordance with one of the claims 1, 3 or 5, wherein the outlet (15), or the outlets (15), of the second lumen (5) are located in the proximity of the distal end (13) of the catheter (1), specifically at a distance of 0 mm to 60 mm from the distal end (13) of the catheter (1).

8. Catheter or apparatus in accordance with one of the preceding claims, wherein the distance between the outlet or outlets (15) of the second lumen (5) and the outlet or outlets (21) of the third lumen (7) is approximately the length of the left ventricle (24), and is specifically 60 mm to 140 mm.

9. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) can be filled with gas or fluid.

10. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) is conical in its expanded state, and wherein the diameter of the balloon (9) increases with increasing distance from the distal end (13) of the catheter (1).

11. Catheter or apparatus in accordance with one of the preceding claims, wherein the catheter (1) has X-ray reflective markings (17, 19) in the area of the outlets (21) of the third lumen (7) and/or in the area of the outlets (15) of the second lumen (5).

during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

20. Apparatus in accordance with one of the claims 3 to 19, wherein the pressure in the environment of the balloon (9) and/or the outlets (15, 21) can be measured through first lumen (3), second lumen (7) and/or third lumen (7).

21. Apparatus in accordance with one of the claims 3 to 20, wherein pharmacologically effective substances, specifically for thrombolytic therapy following acute cardiac infarction, are injected through second lumen (5) and/or third lumen (7).

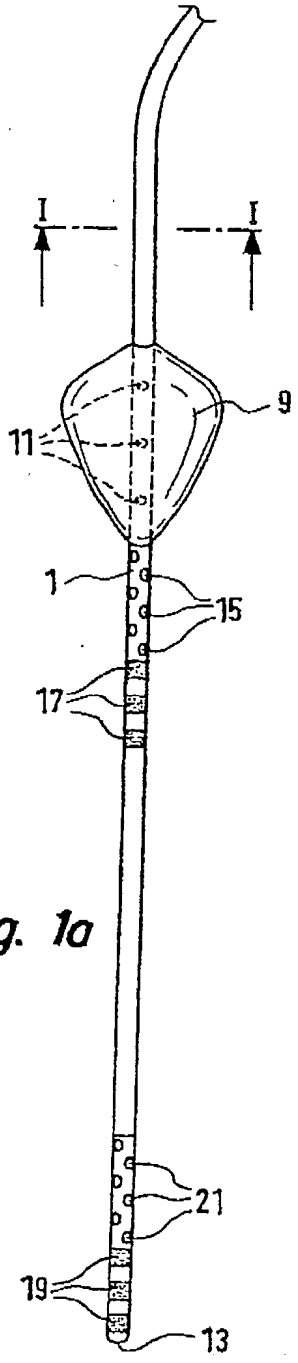


Fig. 1a

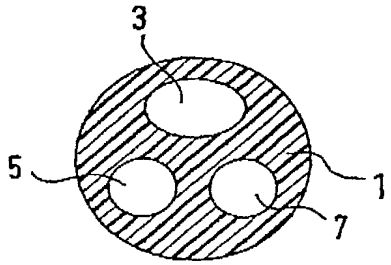


Fig. 1b

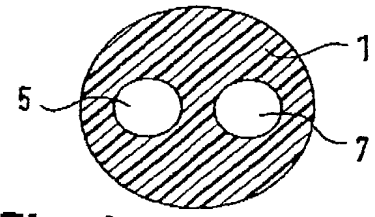


Fig. 1c

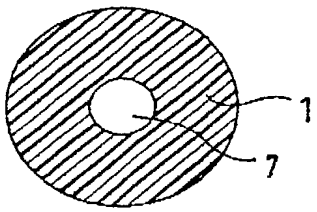


Fig. 1d

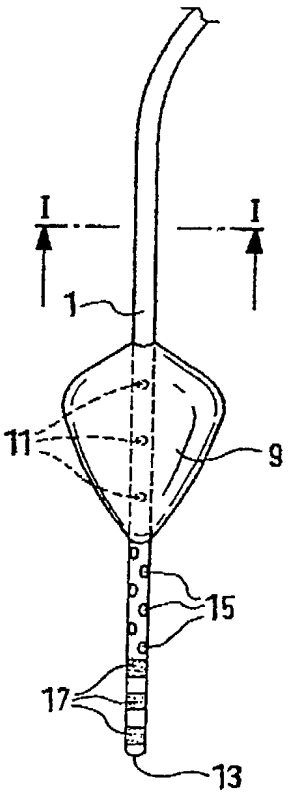


Fig. 2a

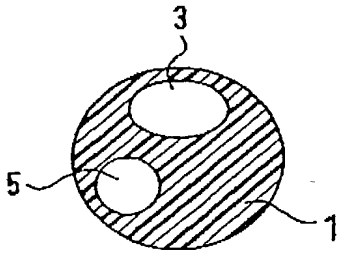


Fig. 2b

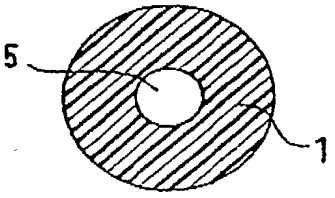


Fig. 2c

Fig. 3b

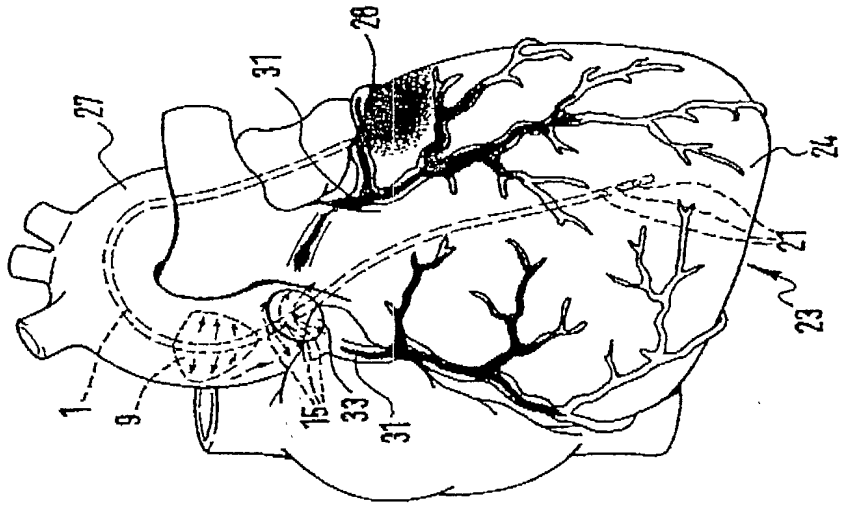


Fig. 3a

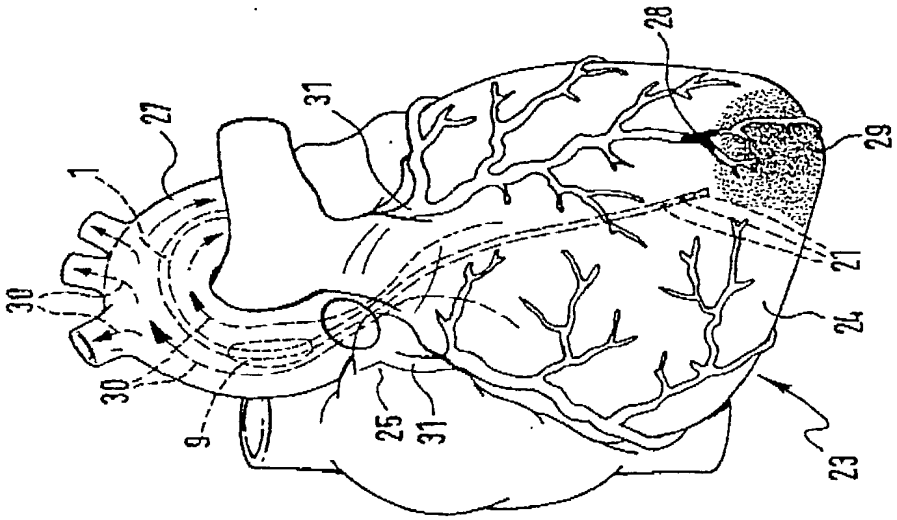
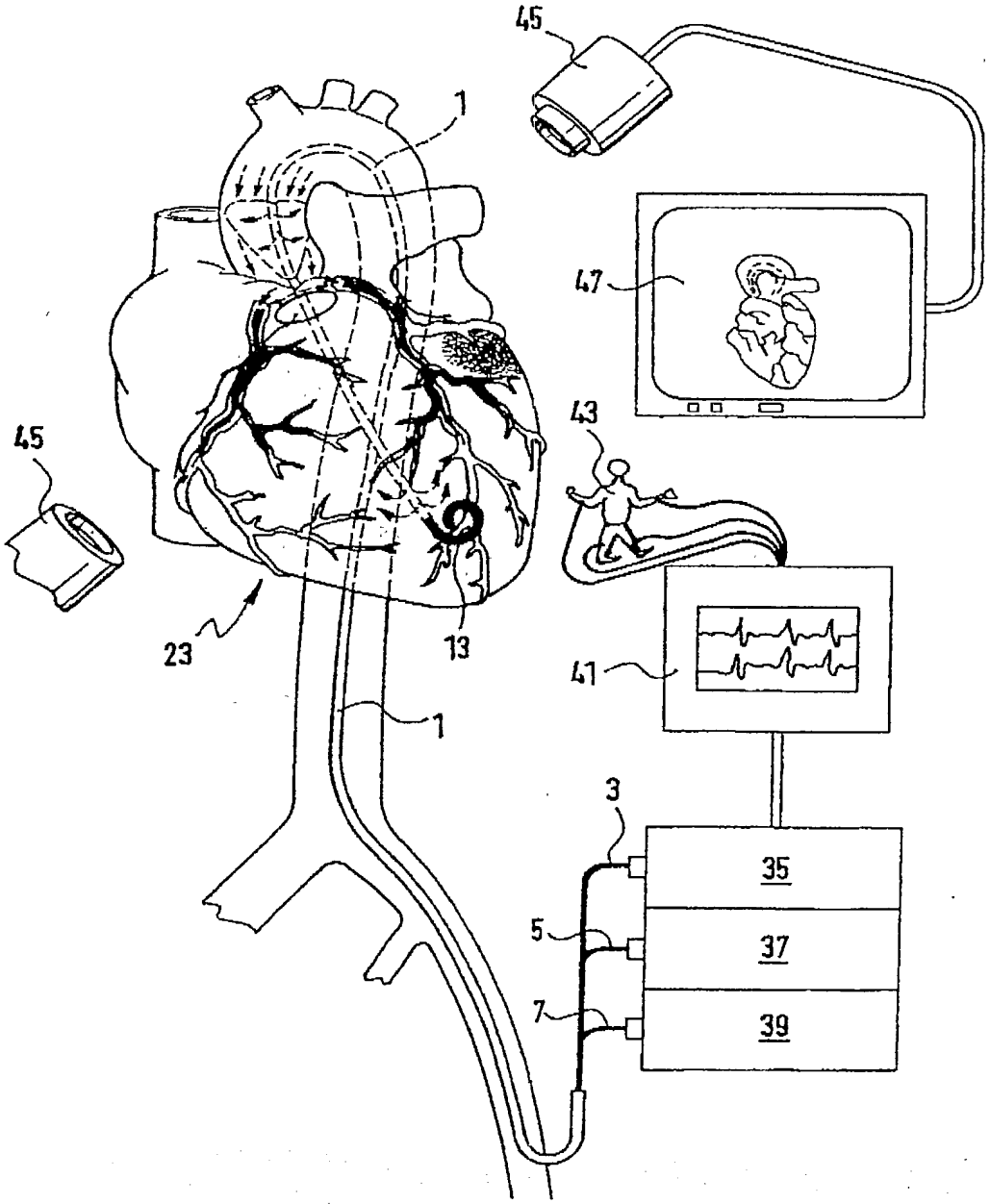
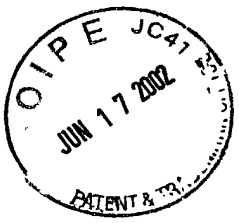


Fig. 4





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Catheter for Carrying Out the Combined Examination of the Left Ventricle and of the Right and Left Coronary Arteries

BACKGROUND Description

The invention takes as its point of departure a multi-lumen catheter having an inflatable balloon, where the balloon connects to a first lumen, and having a second lumen, where the second lumen has at least one outlet, and a device for perfusing a contrast medium with a multi-lumen catheter having an inflatable balloon, where the balloon connects over a first lumen with a balloon pump, and having a second lumen where the second lumen has at least one outlet which connects over the second lumen to a first contrast medium pump.

In order to be able to perform an X-ray examination of the left ventricle and the left and right coronary arteries, or respectively other aortic orifices or aortocoronary bypasses, a radiopaque X-ray substance is pumped by means of a catheter into the area of the heart to be examined. Using an X-ray camera, the volume, or the change in volume respectively, of the left cardiac chamber, hereafter called the left ventricle, and the blood circulation in the coronary arteries can be shown on an X-ray screen.

Examinations of this kind are used for the combined sequential angiographic presentation of the left cardiac chamber and coronary arteries if there is a clinical suspicion of coronary heart disease, diseases of the myocardium of the left cardiac chamber (e.g. condition following myocardial infarction with reduced contractility of the myocardium), vitiation and similar conditions.

At the present time several catheters are used in sequence when these examinations are performed, when one catheter is first inserted into the arteria femoralis or the arteria brachialis through an entry in the groin and then advanced into the left ventricle. Through a passage – henceforth referred to as a lumen – in the catheter, having an opening at the tip of the catheter, contrast medium is injected under pressure, while the filling of the left ventricle during several heart cycles is brought up on a screen by means of an X-ray camera.

The second part of the examination consists of introducing a second, specially shaped catheter into the aorta, in place of the first catheter, for probing the left coronary artery. The current position of the catheter tip as it is advanced through the aorta can be tracked by using radiopaque materials until it reaches the bulbus aortae. If the correct position in the ostium (opening of the blood vessel) of the coronary artery is probed and the catheter is securely positioned, the entire mass of contrast medium is injected under high pressure into the coronary artery. The left coronary artery shows up on the X-ray image as a dark, intertwined blood vessel. Multiple repetitions of the injection of contrast medium, or several different X-ray projections, are necessary for complete viewing. The purpose of the examination is to discover, among other things, restrictions caused by coronary sclerosis which are obstructing the arterial supply of blood and which can lead to angina pectoris and, in later stages, to a cardiac infarction.

In a similar way, the right coronary artery is also shown in a third step on the screen with the aid of a third, similarly specially shaped catheter. When necessary, the often difficult search for and portrayal of an existing aortocoronary bypass follows.

The disadvantage of the catheters for cardiac examinations in the prior art and of the devices for perfusing a contrast medium with a multi-lumen catheter is that they are suitable only for examining one area of the heart – left ventricle, right or left coronary artery. Consequently, several catheters have to be used in the course of a normal, complete examination, which increases the time required for the examination and thus the physical and mental stress on the patient as well as the exposure to X-rays of the patient, physician and attending staff. The risk of infection is also increased, since at least three catheters have to be inserted.

Finally, because of the complicated process of changing of catheters, the necessary multiple X-ray positional checks and multiple injections of contrast medium, the examination time is long and the exposure to X-rays for the patient, physician and attending staff is high. (Physician and, to some extent, assisting staff must remain standing at the examination table during the X-ray examinations, whereby they are exposed to X-ray radiation. The inventive catheter not only

shortens the overall examination but possibly also allows stepping away briefly from the examination table during the time of the X-ray examinations.

The specially shaped catheters for examining the coronary arteries in the prior art have to be introduced into the coronary arteries and there, particularly with arteriosclerotic plaques close to the arterial trunk , they can result in a rupture and, in extreme cases, to acute infarction. Moreover, the danger of arterial dissection and a relative ischemia exists, caused by the highly concentrated, oxygen-poor contrast medium. With unfavorable anatomical conditions or variants thereof, or with a condition following an aortocoronary bypass operation it may also be necessary to introduce more than two catheters to examine the coronary arteries.

In order to obtain an improved image of the area of the heart being examined, it is proposed in WO 91/08791 that the areas of the heart not being examined be segregated by suitable blocking means from the area of the heart being examined. As a result, the concentration of contrast medium in the area of the heart to be examined can be increased and thus improve the image of the area of the heart to be examined. One possible means of segregating one area of the heart from another area is an inflatable balloon, which is located, for example, at the tip of the catheter and can be dilated by a pump connected by means of a lumen in the catheter to the balloon. If a catheter of this kind with its tip is introduced into a coronary artery and the balloon is inflated, almost no blood continues to flow out of the aortic bulb into the blocked off coronary artery. This increases the blood circulation in the other coronary artery or the concentration of the contrast medium injected into the aortic bulb in the other coronary artery. The image of a coronary artery on the screen is somewhat improved by this cardiac catheter; however, the basic problem remains that in order to examine the left ventricle and both coronary arteries at least three catheters have to be inserted. Furthermore, the blocking off, even if only for a short time, of one coronary artery results in a temporary undersupply of the blocked off coronary artery and the resulting undesirable potential consequences for the patient. As with conventional single-lumen catheters for showing individual coronary arteries, the same risks exist here for the complicated probing of the arterial entrances with the imminent risk of the rupture of unstable plaques.

A urological catheter is known from DE 295 03 895 U1 having two lumina and a balloon inflatable and deflatable through one of the two lumina. In its inflated state the balloon is used to hold the catheter in position in the urinary tract.

SUMMARY

The object of the invention to provide a catheter and a device for perfusing a contrast medium, which make possible a short, and for the patient less stressful, examination of the left ventricle and a non-selective image of both coronary arteries. Furthermore, the examination shall be less dangerous for the patient, the exposure to X-rays for patient, physician and attending staff shall be reduced and finally an improved representation of the areas of the heart being examined shall be obtained.

This object is achieved under the invention by a multi-lumen catheter having an expandable balloon, where the balloon is connected to a first lumen, and having a second lumen, where the second lumen has at least one outlet, where the outlet, or outlets, of the second lumen are located between the balloon and a distal end of the catheter, and where the catheter is used for the angiography of coronary arteries, aortocoronary bypasses and other exits from the aorta and its branches.

This inventive catheter possesses the advantage that both the left ventricle and also both coronary arteries can be examined with it, so that the risk of infection for the patient is reduced as a result of eliminating the exchange of catheters. Moreover, it is not necessary to invade the coronary artery with the tip of the catheter, since, in its expanded state, the balloon prevents the flow of blood and contrast medium out of the aorta and thus results in an increased concentration of contrast medium in the area of the aortic bulb and of the coronary artery. While the balloon is being expanded, its increase in volume even results in an increased physiological reflux of blood from the area of the aortic bulb into the coronary arteries. The penetration of contrast medium injected into the coronary arteries simultaneously with the expansion of the balloon is thereby improved and thus their depiction on the screen. By dispensing with the invasion of the coronary arteries with a catheter tip, the risk of arteriosclerotic plaques close to the arterial trunk becoming detached and consequently of an acute infarction is enormously reduced. Moreover, there is no damage to the endothelium of the coronary arteries, which

must be accepted even with an uncomplicated probe and which, in turn, can become the start of an atherosclerotic restriction of the blood vessel. The potential negative consequences of the temporary undersupply of one coronary artery as the result of a blocking means – as proposed in the case of WO 91/08791 – are also reduced.

In a different version of the invention it is envisioned that the catheter has a third lumen having at least one outlet and that the outlet, or outlets, of the third lumen are located between the outlet, or outlets, of the second lumen and the distal end of the catheter, so that several areas of the heart can be examined without the necessity of changing the position of the catheter relative to the heart.

The object stated at the beginning is also achieved by a device for perfusing a contrast medium with a multi-lumen catheter, having an expandable balloon, where the balloon is connected to a balloon pump through a first lumen, having a second lumen, where the second lumen has at least one outlet which is connected to a first contrast medium pump or syringe through the second lumen, and where the outlet, or outlets, of the second lumen are located between the balloon and the distal end of the catheter.

Supplemental to the invention it is envisioned that the catheter of the inventive apparatus has a third lumen connected to a second contrast medium pump or syringe having at least one outlet and that the outlet, or outlets, of the third lumen are located between the outlet(s) of the second lumen and the distal end of the catheter. The advantages of the inventive apparatus and its supplement are the same as the aforementioned advantages of the catheters, so that reference is made to the corresponding passages.

Supplemental to the invention it is envisioned that the outlet, or outlets, of the second lumen are located in the proximity of the balloon, specifically at a distance of 0 to 60 mm from the balloon, so that the contrast medium can be injected above the aortic valve into the bulbus aortae [aortic bulb] thereby enriching the contrast medium in the coronary arteries, while the balloon at least partially inhibits the outflow of blood and contrast medium into the aorta ascendens. For this, the balloon is positioned immediately above the aortic bulb and the balloon is expanded in synchronization with the injection of the contrast medium.

Supplemental to the invention it is envisioned that the outlet, or outlets, of the third lumen are located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 50 mm from the distal end of the catheter, so that contrast medium can be injected into the left ventricle for viewing.

One supplement to the invention provides for the outlet, or outlets, of the second lumen to be located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 60 mm from the distal end of the catheter, so that the catheter is pushed forward into the left ventricle to examine the left ventricle and then the contrast medium can be injected in the interior of the left ventricle below the aortic valve.

In another embodiment of the invention it is envisioned that the distance between the outlet(s) of the second lumen and the outlet(s) of the third lumen is approximately equal to the inside longitudinal diameter of the left ventricle and is specifically 60 mm to 140 mm, so that both the left ventricle and also the coronary arteries can be filled with contrast medium with the catheter in one position.

In another embodiment of the invention the balloon can be filled with gas or fluid, so that an economical and unproblematic medium is available to fill the balloon.

Another embodiment of the invention provides for the balloon to be conical in its expanded state and for the diameter of the balloon to increase with increasing distance from the distal end of the catheter, so that basically it is also possible to use the balloon for a controlled extended inflation of about 4 to 5 seconds duration. For this the lumen of the aorta is not reduced completely but up to about two-thirds of the diameter previously determined by echocardiography. This ensures that adequate residual blood circulation is preserved in all peripheral and specifically cranial arteries.

Another variation of the invention envisions that the catheter in the area of the outlets of the third lumen and/or in the area of the outlets of the second lumen has X-ray reflective markings, or respectively is radiopaque, so that it is possible to position the inventive catheter in the heart simply and reliably.

In another embodiment of the invention, the catheter is bent at its end, so that it cannot penetrate the coronary arteries because of its pigtail, circular or spiral shape and cannot cause any other damage to the heart.

In another embodiment of the inventive apparatus, the balloon pump can be controlled from EKG equipment, so that the increase in concentration of the contrast medium can be implemented with the least possible detriment to the activity of the heart, or to the patient's circulation respectively.

Further supplemental to the inventive apparatus, the balloon pump blows during specific phases of the heart, specifically during systole or diastole, or a phase range of the heart cycle selected independently thereof, or continuously over several heart cycles, so that the penetration of contrast medium into the coronary arteries is encouraged; however, systolic blood flow remains unrestricted. This effect, which results from the increase in volume of the balloon, matches the effect with which blood is pumped into the coronary arteries during diastole. The result is a very realistic picture of the coronary arteries, because the procedure is taking place in the natural pressure range. For this reason blood flow conditions and possible constrictions in the coronary arteries are, by and large, natural, and their true significance can be shown correspondingly. Artifacts caused by turbulence and pressure-induced expansions of the vessel wall are largely eliminated. Furthermore, at no time during the examination is the flow through the coronary arteries reduced; on the contrary, it is increased and thus the relative ischemia caused by the highly concentrated, oxygen-poor contrast medium is at least reduced.

In other embodiments of the invention, the balloon pump empties the balloon again during specific heart phases, specifically during systole or diastole or a phase range selected independently thereof or continuously over several heart cycles, so that the arteria renalis and other exits from the aorta can be shown.

Other variations of the invention envision that the first and the second contrast medium pump can be controlled from EKG equipment and that the first contrast medium pump for the second lumen and the second contrast medium pump for the third lumen supply contrast medium to the catheter during specific phases of cardiac activity, specifically diastolic, or continuously over several heart cycles

(heartbeats), so that with the economical use of contrast medium in the areas of the heart to be examined a highest possible local concentration of contrast medium is available, and thus a good representation of the areas of the heart to be examined, showing the blood circulation conditions in the heart, is possible on the X-ray screen.

In a variation of the invention it is envisioned that through first lumen, second lumen and/or third lumen the pressure in the environment of the balloon and/or the outlet is measurable, so that a measurement of the pressures in left ventricle and aortic bulb, which should precede a coronary angiography, is possible without additional stress for the patient and almost without prolonging the overall duration of the examination.

In a further embodiment of the invention pharmacologically effective substances, specifically for thrombolytic therapy following an acute cardiac infarction, are injected, so that the pharmacologically effective substances attain improved concentration compared with systemic administration.

BRIEF DESCRIPTION OF THE DRAWING

Additional advantages and advantageous embodiments of the invention can be found in the following drawing, the description and the patent claims. In the drawing:

Figures 1a–1d show in various

Figure 1 shows a first embodiment of an inventive catheter with cross sections;

Figures 2a–2c shows in various

Figure 2 shows a second embodiment of an inventive catheter with cross sections;

Figures 3a and 3b show

Figure 3 shows a schematic representation of the heart with an inventive catheter; and

Figure 4 shows: a heart with an inventive apparatus.

1a DETAILED DESCRIPTION

Figure 1 shows a first embodiment of an inventive catheter 1 having three lumina. Figure 1b shows the catheter 1 along the section line I-I. In this representation a first lumen 3, a second lumen 5 and a third lumen 7 can be seen. A balloon 9 is inflated, or deflated respectively, through the first lumen 3 with a fluid or a gas. In Figure 1 the balloon 9 is shown in the inflated or expanded state. The connection between the first lumen 3 and balloon 9 is invoked through outlets 11. It can also be clearly seen that the balloon 9 in the inflated state has a conical or

truncated cone shape, where the diameter of the balloon 9 increases with increasing distance from a distal end 13 of the catheter 1.

Between balloon 9 and a distal end 13 of the catheter 1, there are additional outlets 15 in the immediate proximity of the balloon 9. These outlets 15 are connected to the second lumen 5 of the catheter 1. Contrast medium which emerges below the balloon 9 from the outlets 15 can be pumped through the second lumen 5. In the area of the outlets the catheter 1 has a cross section in accordance with Figure 1c. Only the second lumen 5 and third lumen 7 are still present . In the immediate proximity of the outlets 15 there are markings 17 which reflect X-rays and thus can be detected on an X-ray image. With the help of these markings 17 the inventive catheter 1 can be positioned in the patient's heart in a specific way such that the outlets 15 end up in the area of the aortic bulb. When a contrast medium is delivered in this position through the second lumen 5 and this contrast medium exits from the outlets 15, the contrast medium reaches the coronary arteries during diastole and allows them to be shown on the screen. The balloon 9 is expanded simultaneously to support this procedure.

There are additional markings 19 at the distal end 13 of the catheter 1. With the help of markings 19, which reflect X-rays, the distal end 13 can be positioned in the left ventricle, and the position of the distal end 13 can be verified on the X-ray screen. Also in the immediate proximity of the distal end 13 there are outlets 21 which are connected to the third lumen 7. The cross section through the catheter 1 in the area of the outlets 21 is shown in Figure 1d. The distance between the outlets 15 and the outlets 17 approximately matches the length of the left ventricle, so that, when the distal end 13 of the catheter 1 is introduced into the left ventricle, the outlets 15 are automatically positioned in the area of the aortic bulb. What is accomplished is that both the left ventricle and the coronary arteries can be filled with contrast medium without having to change the position of the catheter 1 with respect to the heart.

Figure 2 shows a second embodiment of an inventive catheter 1. The same components were given the same reference numbers. Reference is made to the description of Figure 1 with respect to an explanation thereof.

The fundamental difference compared with the first embodiment is that there is no third lumen. For this reason catheter 1 can be configured with a smaller diameter, which makes its introduction through a shunt in the groin easier, or respectively makes a smaller shunt possible. Furthermore, manufacturing costs are reduced. An additional difference is that balloon 9 is located in the immediate proximity of the distal end 13 of the catheter 1. In order to examine the left ventricle, the catheter is pushed through the aorta into the left ventricle until the distal end 13 of the catheter lies against the side of the left ventricle opposite the aortic valves or is in the immediate proximity of this side. In this position the balloon is deflated, that is, it is lying against catheter 1 and has no function in this position. The examination of the left ventricle is undertaken in the usual way. When this examination is concluded the catheter is retracted somewhat, just far enough until the outlets 15 are in the area of the aortic bulb or coronary arteries respectively. In this position the balloon 9 is positioned in the aorta and can increase the concentration of contrast medium in the coronary arteries, as described above. It is much simpler to contrive to move the catheter 1 during an examination than to change a catheter and furthermore it can be carried out more quickly, so that examination time and stress on the patient are reduced.

Figure 3a shows a heart 23 in systole with the inventive catheter 1. The catheter 1 extends into the left ventricle 24, while the balloon 9 is positioned above the aortic bulb 25. During systole the balloon 9 is deflated, that is, it is lying basically flat against the catheter 1 and thus causes only minor resistance to the outflowing blood in the aorta 27, indicated by arrows 30. Also indicated is a coronary stenosis 28, which results in the tissue 29 that lies behind the coronary stenosis 28 in the direction of flow being poorly supplied with blood. The discovery of such coronary stenoses shall be made easier with the assistance of the inventive catheter 1 by delivering a contrast medium (not shown) into the coronary arteries 31.

This procedure is depicted in Figure 3b. It shows the heart during diastole, that is, the left ventricle 24 is increasing its volume and thus wants to draw blood back out of the aorta 27. This is prevented by the aortic valves 33 which are closed because of the pressure differential between left ventricle 24 and aorta 27.

The incipient backflow of blood out of the aorta 27 in the direction of the left ventricle results in blood, or contrast medium respectively, which is leaving the outlets 15 of the catheter (see Figure 1 and Figure 3), flowing into the coronary arteries. In Figure 3b the contrast medium was suggested by showing the coronary arteries 31 filled with contrast medium in black. The balloon 9 is inflated during diastole so that its volume is enlarged and it thus supports, or reinforces, the return flow of blood, or contrast medium respectively, from the area of the aortic bulb as far as the balloon 9 into the coronary arteries. The expansion of the balloon is indicated in Figure 3b by arrows. As a result, and because the drainage of contrast medium through the aorta is prevented, the concentration of contrast medium in the area of the aortic bulb and the coronary arteries is increased compared with traditional cardiac catheters, without degrading the oxygen supply to the coronary arteries.

When the left ventricle is to be examined, the balloon is deflated and contrast medium is pumped out of the outlets 21 (see Figure 1) into the left ventricle 24. From Figure 3 it is clear that left ventricle 24 as well as both coronary arteries 31 can be examined without the necessity of changing the position of catheter 1. This simplifies the examination, and the time required is drastically reduced by restricting X-ray photographs for checking the position to a minimum. Consequently, the stress from X-rays for patient, physician and attending staff is also reduced. At the same time the images of the areas of the heart being examined 23 are improved.

Figure 4 shows a heart 23 with catheter 1 inserted and the other components of an inventive apparatus for perfusing contrast media. The first lumen 3 of catheter 1 is connected to a balloon pump 35. The second lumen 5 is connected to a first contrast medium pump 37, while the third lumen 7 is connected to a second contrast medium pump 39. The balloon pump 35 and first and second contrast medium pumps 37 and 39 are controlled from EKG equipment 41, which is hooked up to the patient 43, who is shown in highly simplified form. As the result of this arrangement, the balloon 9 is deflated during systole and inflated during diastole. Additionally the moment for perfusing the contrast medium can be selected.

The contrast medium in the heart 23 can be shown on a screen 47 by means of an X-ray camera 45. The embodiment of the catheter 1 shown in Figure 4

has a so-called pigtail, meaning that its distal end 13 is curved in the shape of a spiral, so that damage to the heart wall or unintentional penetration of one of the coronary arteries 32 is prevented.

All the features presented in the description, the following claims and the drawing can be essential to the invention both individually as well as in any combination with each other.

What is Claimed is:

What Is Claimed Is:

1. Multi-lumen catheter having an expandable balloon (9), where the balloon (9) is connected to a first lumen (3), and having a second lumen (5), where the second lumen (5) has at least one outlet (15), where the outlet (15), or the outlets (15), of the second lumen (5) are located between the balloon (9) and a distal end (13) of the catheter (1), characterized in that the catheter is used for the angiography of coronary arteries, aortocoronary bypasses and other exits of the aorta and its branches.

2. Catheter in accordance with claim 1, wherein the catheter (1) has a third lumen (7) having at least one outlet (21), and wherein the outlet (21), or the outlets (21), of the third lumen (7) are located between the outlet or outlets (15) and the distal end (13) of the catheter (1).

3. Apparatus for perfusing a contrast medium having a multi-lumen catheter (1) with an expandable balloon (9), where the balloon (9) is connected to a balloon pump (35) by means of a first lumen (3), having a second lumen (5), where the second lumen (5) has at least one outlet (15) which is connected through the second lumen to a first contrast medium pump or syringe (37), characterized in that the outlet (15), or the outlets (15), of the second lumen are located between the balloon (9) and the distal end (13) of the catheter (1).

4. Device in accordance with claim 3, wherein the catheter (1) has a third lumen (7) connecting to a second contrast medium pump or syringe (39) having at least one outlet (21), and wherein the outlet (21), or the outlets (21), of the third lumen (7) are located between the outlet or outlets (15) of the second lumen (5) and the distal end (13) of the catheter (1).

5. Catheter or apparatus in accordance with one of the preceding claims, wherein the outlet (15), or the outlets (15), of the second lumen (5) are

located in the proximity of the balloon (9), specifically at a distance of 0 mm to 60 mm from the balloon (9).

6. Catheter or apparatus in accordance with one of the preceding claims, wherein the outlet (21), or the outlets (21), of the third lumen (7) are located in the proximity of the distal end (13) of the catheter (1) specifically at a distance of 0 mm to 50 mm from the distal end of the catheter (1).

7. Catheter or apparatus in accordance with one of the claims 1, 3 or 5, wherein the outlet (15), or the outlets (15), of the second lumen (5) are located in the proximity of the distal end (13) of the catheter (1), specifically at a distance of 0 mm to 60 mm from the distal end (13) of the catheter (1).

8. Catheter or apparatus in accordance with one of the preceding claims, wherein the distance between the outlet or outlets (15) of the second lumen (5) and the outlet or outlets (21) of the third lumen (7) is approximately the length of the left ventricle (24), and is specifically 60 mm to 140 mm.

9. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) can be filled with gas or fluid.

10. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) is conical in its expanded state, and wherein the diameter of the balloon (9) increases with increasing distance from the distal end (13) of the catheter (1).

11. Catheter or apparatus in accordance with one of the preceding claims, wherein the catheter (1) has X-ray reflective markings (17, 19) in the area of the outlets (21) of the third lumen (7) and/or in the area of the outlets (15) of the second lumen (5).

12. Catheter or apparatus in accordance with one of the preceding claims, wherein the catheter (1) is bent at its distal end (13) – specifically in the shape of a pigtail, circle or spiral.

13. Apparatus in accordance with one of the preceding claims, wherein the balloon pump (3) can be controlled from EKG equipment.

14. Apparatus in accordance with one of the preceding claims 3 to 13, wherein the balloon pump (35) inflates the balloon (9) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

15. Apparatus in accordance with one of the claims 3 to 13, wherein the balloon pump (35) empties the balloon (9) again during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

16. Apparatus in accordance with one of the claims 3 to 15, wherein the first contrast medium pump (37) can be controlled from EKG equipment.

17. Apparatus in accordance with one of the claims 3 to 16, wherein the first contrast medium pump (37) conveys contrast medium into the catheter (1) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

18. Apparatus in accordance with one of the claims 3 to 17, wherein the second contrast medium pump (39) can be controlled from EKG equipment.

19. Apparatus in accordance with one of the claims 3 to 18, wherein the second contrast medium pump (39) conveys contrast medium into the catheter (1) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

20. Apparatus in accordance with one of the claims 3 to 19, wherein the pressure in the environment of the balloon (9) and/or the outlets (15, 21) can be measured through first lumen (3), second lumen (7) and/or third lumen (7).

21. Apparatus in accordance with one of the claims 3 to 20, wherein pharmacologically effective substances, specifically for thrombolytic therapy following acute cardiac infarction, are injected through second lumen (5) and/or third lumen (7).

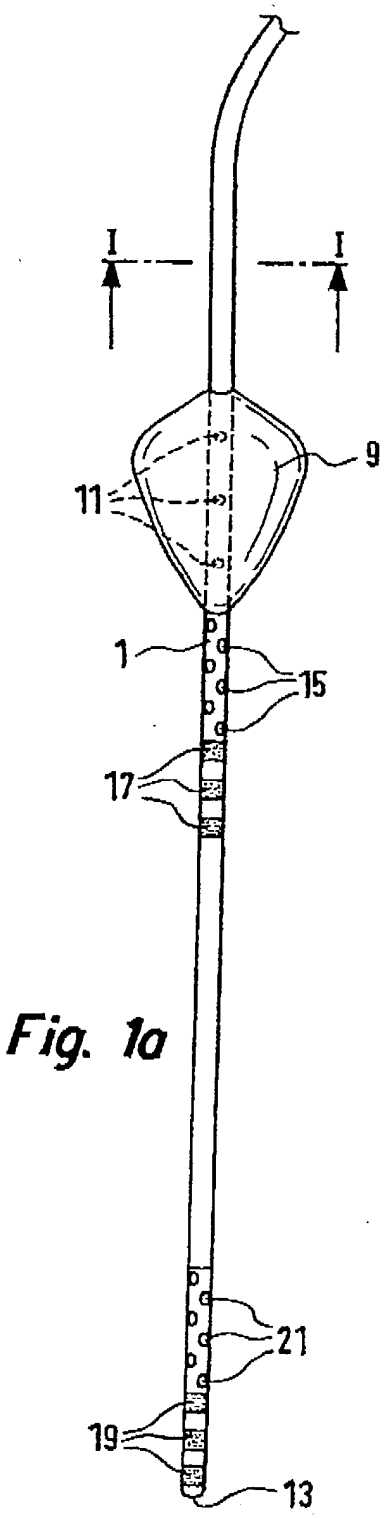


Fig. 1a

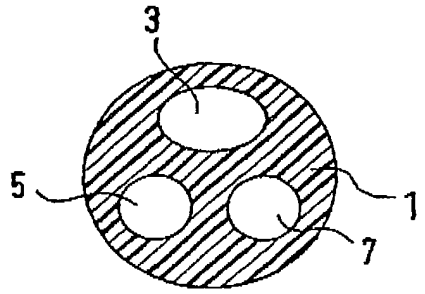


Fig. 1b

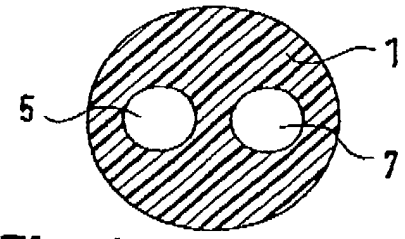


Fig. 1c

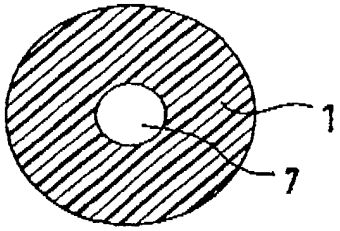


Fig. 1d

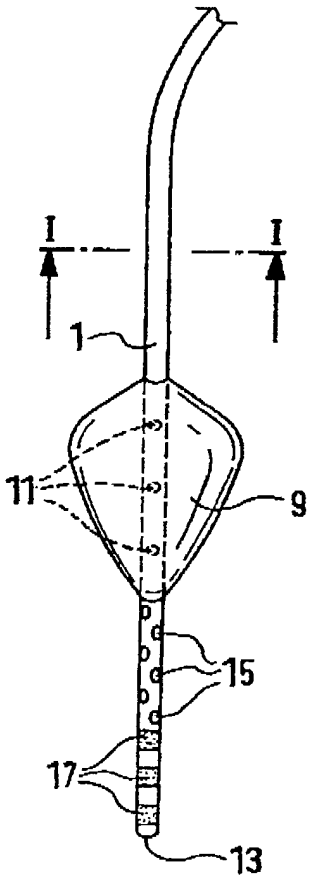


Fig. 2a

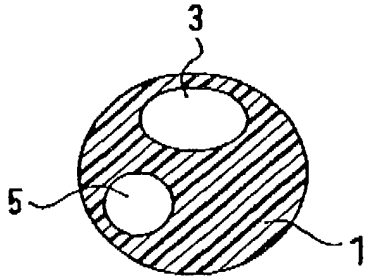


Fig. 2b

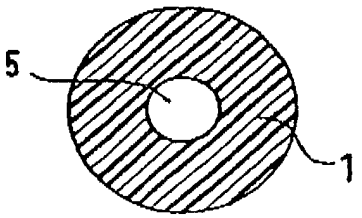


Fig. 2c

Fig. 3b

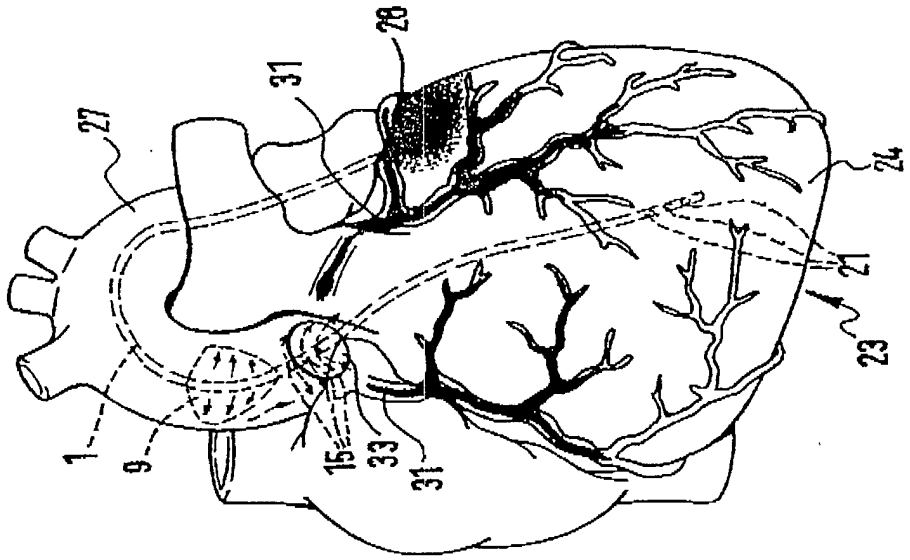


Fig. 3a

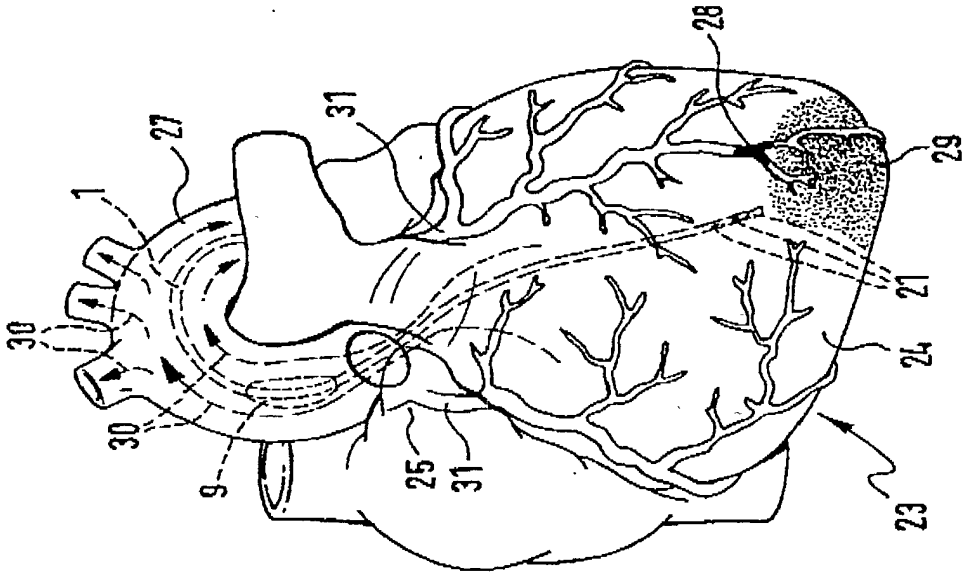
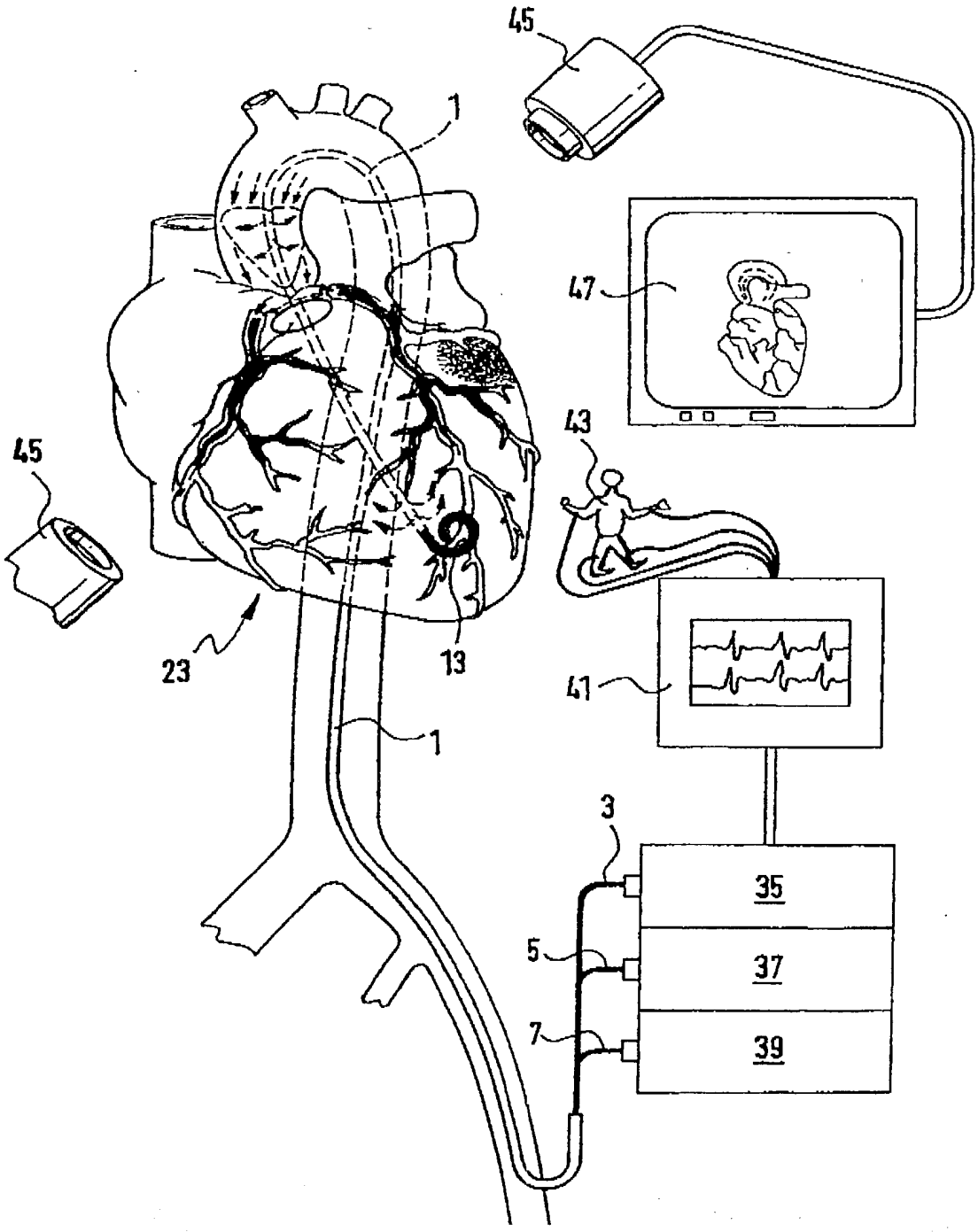
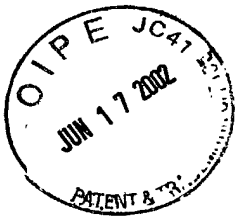


Fig. 4





Catheter for Carrying Out the Combined Examination of the Left Ventricle and of the Right and Left Coronary Arteries

Description

The invention takes as its point of departure a multi-lumen catheter having an inflatable balloon, where the balloon connects to a first lumen, and having a second lumen, where the second lumen has at least one outlet, and a device for perfusing a contrast medium with a multi-lumen catheter having an inflatable balloon, where the balloon connects over a first lumen with a balloon pump, and having a second lumen where the second lumen has at least one outlet which connects over the second lumen to a first contrast medium pump.

In order to be able to perform an X-ray examination of the left ventricle and the left and right coronary arteries, or respectively other aortic orifices or aortocoronary bypasses, a radiopaque X-ray substance is pumped by means of a catheter into the area of the heart to be examined. Using an X-ray camera, the volume, or the change in volume respectively, of the left cardiac chamber, hereafter called left ventricle, and the blood circulation in the coronary arteries can be shown on an X-ray screen.

Examinations of this kind are used for the combined sequential angiographic presentation of the left cardiac chamber and coronary arteries if there is a clinical suspicion of coronary heart disease, diseases of the myocardium of the left cardiac chamber (e.g. condition following myocardial infarction with reduced contractility of the myocardium), vitiation and similar conditions.

At the present time several catheters are used in sequence when these examinations are performed, when one catheter is first inserted into the arteria femoralis or the arteria brachialis through an entry in the groin and then advanced into the left ventricle. Through a passage – henceforth referred to as a lumen – in the catheter, having an opening at the tip of the catheter, contrast medium is injected under pressure, while the filling of the left ventricle during several heart cycles is brought up on a screen by means of an X-ray camera.

The second part of the examination consists of introducing a second, specially shaped catheter into the aorta, in place of the first catheter, for probing the left coronary artery. The current position of the catheter tip as it is advanced through the aorta can be tracked by using radiopaque materials until it reaches the bulbus aortae. If the correct position in the ostium (opening of the blood vessel) of the coronary artery is probed and the catheter is securely positioned, the entire mass of contrast medium is injected under high pressure into the coronary artery. The left coronary artery shows up on the X-ray image as a dark, intertwined blood vessel. Multiple repetitions of the injection of contrast medium, or several different X-ray projections, are necessary for complete viewing. The purpose of the examination is to discover, among other things, restrictions caused by coronary sclerosis which are obstructing the arterial supply of blood and which can lead to angina pectoris and, in later stages, to a cardiac infarction.

In a similar way, the right coronary artery is also shown in a third step on the screen with the aid of a third, similarly specially shaped catheter. When necessary, the often difficult search for and portrayal of an existing aortocoronary bypass follows.

The disadvantage of the catheters for cardiac examinations in the prior art and of the devices for perfusing a contrast medium with a multi-lumen catheter is that they are suitable only for examining one area of the heart – left ventricle, right or left coronary artery. Consequently, several catheters have to be used in the course of a normal, complete examination, which increases the time required for the examination and thus the physical and mental stress on the patient as well as the exposure to X-rays of the patient, physician and attending staff. The risk of infection is also increased, since at least three catheters have to be inserted.

Finally, because of the complicated process of changing of catheters, the necessary multiple X-ray positional checks and multiple injections of contrast medium, the examination time is long and the exposure to X-rays for the patient, physician and attending staff is high. Physician and, to some extent, assisting staff must remain standing at the examination table during the X-ray examinations, whereby they are exposed to X-ray radiation. The inventive catheter not only

shortens the overall examination but possibly also allows stepping away briefly from the examination table during the time of the X-ray examinations.

The specially shaped catheters for examining the coronary arteries in the prior art have to be introduced into the coronary arteries and there, particularly with arteriosclerotic plaques close to the arterial trunk , they can result in a rupture and, in extreme cases, to acute infarction. Moreover, the danger of arterial dissection and a relative ischemia exists, caused by the highly concentrated, oxygen-poor contrast medium. With unfavorable anatomical conditions or variants thereof, or with a condition following an aortocoronary bypass operation it may also be necessary to introduce more than two catheters to examine the coronary arteries.

In order to obtain an improved image of the area of the heart being examined, it is proposed in WO 91/08791 that the areas of the heart not being examined be segregated by suitable blocking means from the area of the heart being examined. As a result, the concentration of contrast medium in the area of the heart to be examined can be increased and thus improve the image of the area of the heart to be examined. One possible means of segregating one area of the heart from another area is an inflatable balloon, which is located, for example, at the tip of the catheter and can be dilated by a pump connected by means of a lumen in the catheter to the balloon. If a catheter of this kind with its tip is introduced into a coronary artery and the balloon is inflated, almost no blood continues to flow out of the aortic bulb into the blocked off coronary artery. This increases the blood circulation in the other coronary artery or the concentration of the contrast medium injected into the aortic bulb in the other coronary artery. The image of a coronary artery on the screen is somewhat improved by this cardiac catheter; however, the basic problem remains that in order to examine the left ventricle and both coronary arteries at least three catheters have to be inserted. Furthermore, the blocking off, even if only for a short time, of one coronary artery results in a temporary undersupply of the blocked off coronary artery and the resulting undesirable potential consequences for the patient. As with conventional single-lumen catheters for showing individual coronary arteries, the same risks exist here for the complicated probing of the arterial entrances with the imminent risk of the rupture of unstable plaques.

A urological catheter is known from DE 295 03 895 U1 having two lumina and a balloon inflatable and deflatable through one of the two lumina. In its inflated state the balloon is used to hold the catheter in position in the urinary tract.

The object of the invention to provide a catheter and a device for perfusing a contrast medium, which make possible a short, and for the patient less stressful, examination of the left ventricle and a non-selective image of both coronary arteries. Furthermore, the examination shall be less dangerous for the patient, the exposure to X-rays for patient, physician and attending staff shall be reduced and finally an improved representation of the areas of the heart being examined shall be obtained.

This object is achieved under the invention by a multi-lumen catheter having an expandable balloon, where the balloon is connected to a first lumen, and having a second lumen, where the second lumen has at least one outlet, where the outlet, or outlets, of the second lumen are located between the balloon and a distal end of the catheter, and where the catheter is used for the angiography of coronary arteries, aortocoronary bypasses and other exits from the aorta and its branches.

This inventive catheter possesses the advantage that both the left ventricle and also both coronary arteries can be examined with it, so that the risk of infection for the patient is reduced as a result of eliminating the exchange of catheters. Moreover, it is not necessary to invade the coronary artery with the tip of the catheter, since, in its expanded state, the balloon prevents the flow of blood and contrast medium out of the aorta and thus results in an increased concentration of contrast medium in the area of the aortic bulb and of the coronary artery. While the balloon is being expanded, its increase in volume even results in an increased physiological reflux of blood from the area of the aortic bulb into the coronary arteries. The penetration of contrast medium injected into the coronary arteries simultaneously with the expansion of the balloon is thereby improved and thus their depiction on the screen. By dispensing with the invasion of the coronary arteries with a catheter tip, the risk of arteriosclerotic plaques close to the arterial trunk becoming detached and consequently of an acute infarction is enormously reduced. Moreover, there is no damage to the endothelium of the coronary arteries, which

must be accepted even with an uncomplicated probe and which, in turn, can become the start of an atherosclerotic restriction of the blood vessel. The potential negative consequences of the temporary undersupply of one coronary artery as the result of a blocking means – as proposed in the case of WO 91/08791 – are also reduced.

In a different version of the invention it is envisioned that the catheter has a third lumen having at least one outlet and that the outlet, or outlets, of the third lumen are located between the outlet, or outlets, of the second lumen and the distal end of the catheter, so that several areas of the heart can be examined without the necessity of changing the position of the catheter relative to the heart.

The object stated at the beginning is also achieved by a device for perfusing a contrast medium with a multi-lumen catheter, having an expandable balloon, where the balloon is connected to a balloon pump through a first lumen, having a second lumen, where the second lumen has at least one outlet which is connected to a first contrast medium pump or syringe through the second lumen, and where the outlet, or outlets, of the second lumen are located between the balloon and the distal end of the catheter.

Supplemental to the invention it is envisioned that the catheter of the inventive apparatus has a third lumen connected to a second contrast medium pump or syringe having at least one outlet and that the outlet, or outlets, of the third lumen are located between the outlet(s) of the second lumen and the distal end of the catheter. The advantages of the inventive apparatus and its supplement are the same as the aforementioned advantages of the catheters, so that reference is made to the corresponding passages.

Supplemental to the invention it is envisioned that the outlet, or outlets, of the second lumen are located in the proximity of the balloon, specifically at a distance of 0 to 60 mm from the balloon, so that the contrast medium can be injected above the aortic valve into the bulbus aortae [aortic bulb] thereby enriching the contrast medium in the coronary arteries, while the balloon at least partially inhibits the outflow of blood and contrast medium into the aorta ascendens. For this, the balloon is positioned immediately above the aortic bulb and the balloon is expanded in synchronization with the injection of the contrast medium.

Supplemental to the invention it is envisioned that the outlet, or outlets, of the third lumen are located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 50 mm from the distal end of the catheter, so that contrast medium can be injected into the left ventricle for viewing.

One supplement to the invention provides for the outlet, or outlets, of the second lumen to be located in the proximity of the distal end of the catheter, specifically at a distance of 0 to 60 mm from the distal end of the catheter, so that the catheter is pushed forward into the left ventricle to examine the left ventricle and then the contrast medium can be injected in the interior of the left ventricle below the aortic valve.

In another embodiment of the invention it is envisioned that the distance between the outlet(s) of the second lumen and the outlet(s) of the third lumen is approximately equal to the inside longitudinal diameter of the left ventricle and is specifically 60 mm to 140 mm, so that both the left ventricle and also the coronary arteries can be filled with contrast medium with the catheter in one position.

In another embodiment of the invention the balloon can be filled with gas or fluid, so that an economical and unproblematic medium is available to fill the balloon.

Another embodiment of the invention provides for the balloon to be conical in its expanded state and for the diameter of the balloon to increase with increasing distance from the distal end of the catheter, so that basically it is also possible to use the balloon for a controlled extended inflation of about 4 to 5 seconds duration. For this the lumen of the aorta is not reduced completely but up to about two-thirds of the diameter previously determined by echocardiography. This ensures that adequate residual blood circulation is preserved in all peripheral and specifically cranial arteries.

Another variation of the invention envisions that the catheter in the area of the outlets of the third lumen and/or in the area of the outlets of the second lumen has X-ray reflective markings, or respectively is radiopaque, so that it is possible to position the inventive catheter in the heart simply and reliably.

In another embodiment of the invention the catheter is bent at its end, so that it cannot penetrate the coronary arteries because of its pigtail, circular or spiral shape and cannot cause any other damage to the heart.

In another embodiment of the inventive apparatus the balloon pump can be controlled from EKG equipment, so that the increase in concentration of the contrast medium can be implemented with the least possible detriment to the activity of the heart, or to the patient's circulation respectively.

Further supplemental to the inventive apparatus, the balloon pump blows during specific phases of the heart, specifically during systole or diastole, or a phase range of the heart cycle selected independently thereof, or continuously over several heart cycles, so that the penetration of contrast medium into the coronary arteries is encouraged; however, systolic blood flow remains unrestricted. This effect, which results from the increase in volume of the balloon, matches the effect with which blood is pumped into the coronary arteries during diastole. The result is a very realistic picture of the coronary arteries, because the procedure is taking place in the natural pressure range. For this reason blood flow conditions and possible constrictions in the coronary arteries are, by and large, natural, and their true significance can be shown correspondingly. Artifacts caused by turbulence and pressure-induced expansions of the vessel wall are largely eliminated. Furthermore, at no time during the examination is the flow through the coronary arteries reduced; on the contrary, it is increased and thus the relative ischemia caused by the highly concentrated, oxygen-poor contrast medium is at least reduced.

In other embodiments of the invention the balloon pump empties the balloon again during specific heart phases, specifically during systole or diastole or a phase range selected independently thereof or continuously over several heart cycles, so that the arteria renalis and other exits from the aorta can be shown.

Other variations of the invention envision that the first and the second contrast medium pump can be controlled from EKG equipment and that the first contrast medium pump for the second lumen and the second contrast medium pump for the third lumen supply contrast medium to the catheter during specific phases of cardiac activity, specifically diastolic, or continuously over several heart cycles

(heartbeats), so that with the economical use of contrast medium in the areas of the heart to be examined a highest possible local concentration of contrast medium is available, and thus a good representation of the areas of the heart to be examined, showing the blood circulation conditions in the heart, is possible on the X-ray screen.

In a variation of the invention it is envisioned that through first lumen, second lumen and/or third lumen the pressure in the environment of the balloon and/or the outlet is measurable, so that a measurement of the pressures in left ventricle and aortic bulb, which should precede a coronary angiography, is possible without additional stress for the patient and almost without prolonging the overall duration of the examination.

In a further embodiment of the invention pharmacologically effective substances, specifically for thrombolytic therapy following an acute cardiac infarction, are injected, so that the pharmacologically effective substances attain improved concentration, compared with systemic administration.

Additional advantages and advantageous embodiments of the invention can be found in the following drawing, the description and the patent claims. In the drawing:

Figure 1 show: a first embodiment of an inventive catheter with cross sections;

Figure 2 shows :a second embodiment of an inventive catheter with cross sections;

Figure 3 shows: a schematic representation of the heart with an inventive catheter; and

Figure 4 shows: a heart with an inventive apparatus.

Figure 1 shows a first embodiment of an inventive catheter 1 having three lumina. Figure 1b shows the catheter 1 along the section line I-I. In this representation a first lumen 3, a second lumen 5 and a third lumen 7 can be seen. A balloon 9 is inflated, or deflated respectively, through the first lumen 3 with a fluid or a gas. In Figure 1 the balloon 9 is shown in the inflated or expanded state. The connection between the first lumen 3 and balloon 9 is invoked through outlets 11. It can also be clearly seen that the balloon 9 in the inflated state has a conical or

truncated cone shape, where the diameter of the balloon 9 increases with increasing distance from a distal end 13 of the catheter 1.

Between balloon 9 and a distal end 13 of the catheter 1 there are additional outlets 15 in the immediate proximity of the balloon 9. These outlets 15 are connected to the second lumen 5 of the catheter 1. Contrast medium which emerges below the balloon 9 from the outlets 15 can be pumped through the second lumen 5. In the area of the outlets the catheter 1 has a cross section in accordance with Figure 1c. Only the second lumen 5 and third lumen 7 are still present . In the immediate proximity of the outlets 15 there are markings 17 which reflect X-rays and thus can be detected on an X-ray image. With the help of these markings 17 the inventive catheter 1 can be positioned in the patient's heart in a specific way such that the outlets 15 end up in the area of the aortic bulb. When a contrast medium is delivered in this position through the second lumen 5 and this contrast medium exits from the outlets 15, the contrast medium reaches the coronary arteries during diastole and allows them to be shown on the screen. The balloon 9 is expanded simultaneously to support this procedure.

There are additional markings 19 at the distal end 13 of the catheter 1. With the help of markings 19, which reflect X-rays, the distal end 13 can be positioned in the left ventricle, and the position of the distal end 13 can be verified on the X-ray screen. Also in the immediate proximity of the distal end 13 there are outlets 21 which are connected to the third lumen 7. The cross section through the catheter 1 in the area of the outlets 21 is shown in Figure 1d. The distance between the outlets 15 and the outlets 17 approximately matches the length of the left ventricle, so that, when the distal end 13 of the catheter 1 is introduced into the left ventricle, the outlets 15 are automatically positioned in the area of the aortic bulb. What is accomplished is that both the left ventricle and the coronary arteries can be filled with contrast medium without having to change the position of the catheter 1 with respect to the heart.

Figure 2 shows a second embodiment of an inventive catheter 1. The same components were given the same reference numbers. Reference is made to the description of Figure 1 with respect to an explanation thereof.

The fundamental difference compared with the first embodiment is that there is no third lumen. For this reason catheter 1 can be configured with a smaller diameter, which makes its introduction through a shunt in the groin easier, or respectively makes a smaller shunt possible. Furthermore, manufacturing costs are reduced. An additional difference is that balloon 9 is located in the immediate proximity of the distal end 13 of the catheter 1. In order to examine the left ventricle, the catheter is pushed through the aorta into the left ventricle until the distal end 13 of the catheter lies against the side of the left ventricle opposite the aortic valves or is in the immediate proximity of this side. In this position the balloon is deflated, that is, it is lying against catheter 1 and has no function in this position. The examination of the left ventricle is undertaken in the usual way. When this examination is concluded the catheter is retracted somewhat, just far enough until the outlets 15 are in the area of the aortic bulb or coronary arteries respectively. In this position the balloon 9 is positioned in the aorta and can increase the concentration of contrast medium in the coronary arteries, as described above. It is much simpler to contrive to move the catheter 1 during an examination than to change a catheter and furthermore it can be carried out more quickly, so that examination time and stress on the patient are reduced.

Figure 3a shows a heart 23 in systole with the inventive catheter 1. The catheter 1 extends into the left ventricle 24, while the balloon 9 is positioned above the aortic bulb 25. During systole the balloon 9 is deflated, that is, it is lying basically flat against the catheter 1 and thus causes only minor resistance to the outflowing blood in the aorta 27, indicated by arrows 30. Also indicated is a coronary stenosis 28, which results in the tissue 29 that lies behind the coronary stenosis 28 in the direction of flow being poorly supplied with blood. The discovery of such coronary stenoses shall be made easier with the assistance of the inventive catheter 1 by delivering a contrast medium (not shown) into the coronary arteries 31.

This procedure is depicted in Figure 3b. It shows the heart during diastole, that is, the left ventricle 24 is increasing its volume and thus wants to draw blood back out of the aorta 27. This is prevented by the aortic valves 33 which are closed because of the pressure differential between left ventricle 24 and aorta 27.

has a so-called pigtail, meaning that its distal end 13 is curved in the shape of a spiral, so that damage to the heart wall or unintentional penetration of one of the coronary arteries 32 is prevented.

All the features presented in the description, the following claims and the drawing can be essential to the invention both individually as well as in any combination with each other.

What Is Claimed Is:

1. Multi-lumen catheter having an expandable balloon (9), where the balloon (9) is connected to a first lumen (3), and having a second lumen (5), where the second lumen (5) has at least one outlet (15), where the outlet (15), or the outlets (15), of the second lumen (5) are located between the balloon (9) and a distal end (13) of the catheter (1), characterized in that the catheter is used for the angiography of coronary arteries, aortocoronary bypasses and other exits of the aorta and its branches.

2. Catheter in accordance with claim 1, wherein the catheter (1) has a third lumen (7) having at least one outlet (21), and wherein the outlet (21), or the outlets (21), of the third lumen (7) are located between the outlet or outlets (15) and the distal end (13) of the catheter (1).

3. Apparatus for perfusing a contrast medium having a multi-lumen catheter (1) with an expandable balloon (9), where the balloon (9) is connected to a balloon pump (35) by means of a first lumen (3), having a second lumen (5), where the second lumen (5) has at least one outlet (15) which is connected through the second lumen to a first contrast medium pump or syringe (37), characterized in that the outlet (15), or the outlets (15), of the second lumen are located between the balloon (9) and the distal end (13) of the catheter (1).

4. Device in accordance with claim 3, wherein the catheter (1) has a third lumen (7) connecting to a second contrast medium pump or syringe (39) having at least one outlet (21), and wherein the outlet (21), or the outlets (21), of the third lumen (7) are located between the outlet or outlets (15) of the second lumen (5) and the distal end (13) of the catheter (1).

5. Catheter or apparatus in accordance with one of the preceding claims, wherein the outlet (15), or the outlets (15), of the second lumen (5) are

located in the proximity of the balloon (9), specifically at a distance of 0 mm to 60 mm from the balloon (9).

6. Catheter or apparatus in accordance with one of the preceding claims, wherein the outlet (21), or the outlets (21), of the third lumen (7) are located in the proximity of the distal end (13) of the catheter (1) specifically at a distance of 0 mm to 50 mm from the distal end of the catheter (1).

7. Catheter or apparatus in accordance with one of the claims 1, 3 or 5, wherein the outlet (15), or the outlets (15), of the second lumen (5) are located in the proximity of the distal end (13) of the catheter (1), specifically at a distance of 0 mm to 60 mm from the distal end (13) of the catheter (1).

8. Catheter or apparatus in accordance with one of the preceding claims, wherein the distance between the outlet or outlets (15) of the second lumen (5) and the outlet or outlets (21) of the third lumen (7) is approximately the length of the left ventricle (24), and is specifically 60 mm to 140 mm.

9. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) can be filled with gas or fluid.

10. Catheter or apparatus in accordance with one of the preceding claims, wherein the balloon (9) is conical in its expanded state, and wherein the diameter of the balloon (9) increases with increasing distance from the distal end (13) of the catheter (1).

11. Catheter or apparatus in accordance with one of the preceding claims, wherein the catheter (1) has X-ray reflective markings (17, 19) in the area of the outlets (21) of the third lumen (7) and/or in the area of the outlets (15) of the second lumen (5).

12. Catheter or apparatus in accordance with one of the preceding claims, wherein the catheter (1) is bent at its distal end (13) – specifically in the shape of a pigtail, circle or spiral.

13. Apparatus in accordance with one of the preceding claims, wherein the balloon pump (3) can be controlled from EKG equipment.

14. Apparatus in accordance with one of the preceding claims 3 to 13, wherein the balloon pump (35) inflates the balloon (9) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

15. Apparatus in accordance with one of the claims 3 to 13, wherein the balloon pump (35) empties the balloon (9) again during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

16. Apparatus in accordance with one of the claims 3 to 15, wherein the first contrast medium pump (37) can be controlled from EKG equipment.

17. Apparatus in accordance with one of the claims 3 to 16, wherein the first contrast medium pump (37) conveys contrast medium into the catheter (1) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

18. Apparatus in accordance with one of the claims 3 to 17, wherein the second contrast medium pump (39) can be controlled from EKG equipment.

19. Apparatus in accordance with one of the claims 3 to 18, wherein the second contrast medium pump (39) conveys contrast medium into the catheter (1) during particular heart phases, specifically during systole or diastole, or an independently selected phase range of the heart cycle, or continuously over several heart cycles.

20. Apparatus in accordance with one of the claims 3 to 19, wherein the pressure in the environment of the balloon (9) and/or the outlets (15, 21) can be measured through first lumen (3), second lumen (7) and/or third lumen (7).

21. Apparatus in accordance with one of the claims 3 to 20, wherein pharmacologically effective substances, specifically for thrombolytic therapy following acute cardiac infarction, are injected through second lumen (5) and/or third lumen (7).

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
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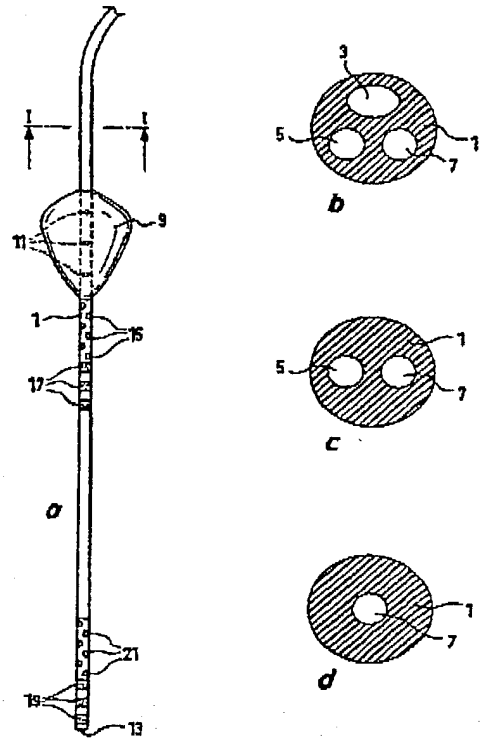
(81) Bestimmungsstaaten *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU,

[Fortsetzung auf der nächsten Seite]

(54) Title: CATHETER FOR CARRYING OUT THE COMBINED EXAMINATION OF THE LEFT VENTRICLE AND OF THE RIGHT AND LEFT CORONARY ARTERIES

(54) Bezeichnung: KATHETER FÜR DIE KOMBINIERTE UNTERSUCHUNG DES LINKEN VENTRIKELS SOWIE DER RECHTEN UND DER LINKEN KORONARARTERIEN



(57) Abstract: The invention relates to a multi-lumen catheter (1) and to a device for perfusing X-ray contrast media or pharmacologically effective substances with which X-ray contrast media or pharmacologically effective substances can be introduced into the left cardiac chamber, the coronary arteries and into other exits of the aorta without changing the catheter. This results in a reduction of the stress to which the patient is subjected, in particular during angiographic examinations, by distinctly reducing the duration of the examination, the exposure to radiation, the risk of examination-related disturbances of cardiac rhythm, and cardiac infarctions as well as the risk of infection.

(57) Zusammenfassung: Es werden ein mehrlumiger Katheter (1) und eine Vorrichtung zur Perfusion von Röntgenkontrastmittel oder pharmakologisch wirksamen Substanzen vorgeschlagen, mit denen Röntgenkontrastmittel oder pharmakologisch wirksame Substanzen in die linke Herzkammer, die Koronararterien und andere Abgänge der Aorta ohne Katheterwechsel eingebracht werden können. Dadurch verringert sich die Belastung des Patienten, insbesondere bei angiographischen Untersuchungen, indem die Dauer der Untersuchung, die Strahlenbelastung, das Risiko von untersuchungsbedingten Herzrhytmusstörungen und Herzinfarkten und das Infektionsrisiko deutlich vermindert werden.

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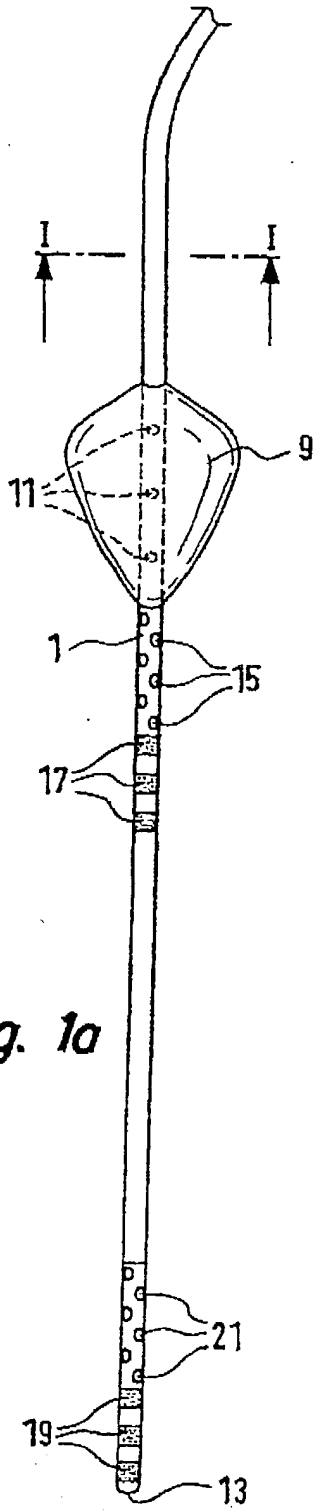


Fig. 1a

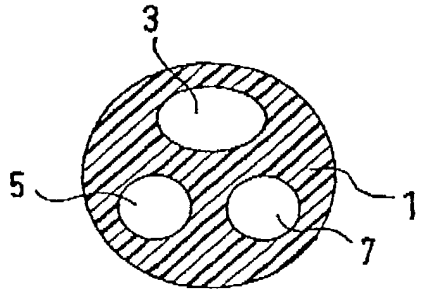


Fig. 1b

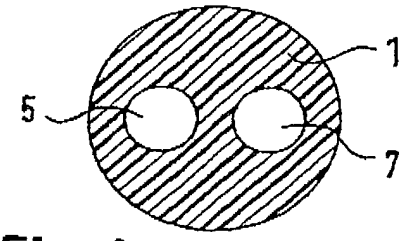


Fig. 1c

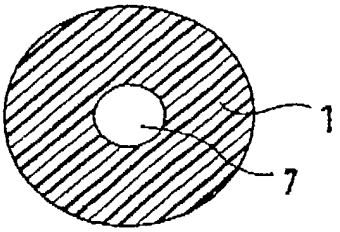


Fig. 1d

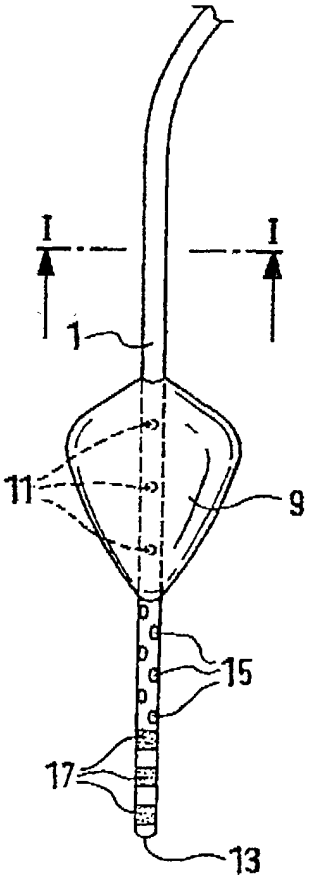


Fig. 2a

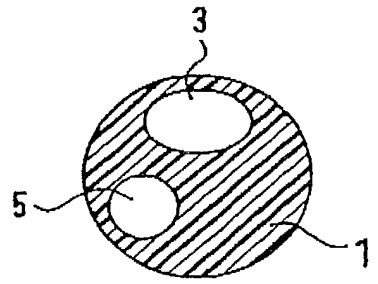


Fig. 2b

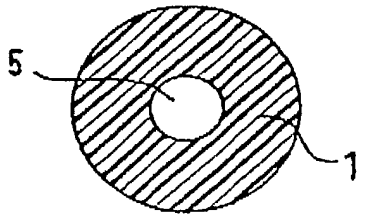


Fig. 2c

Fig. 3b

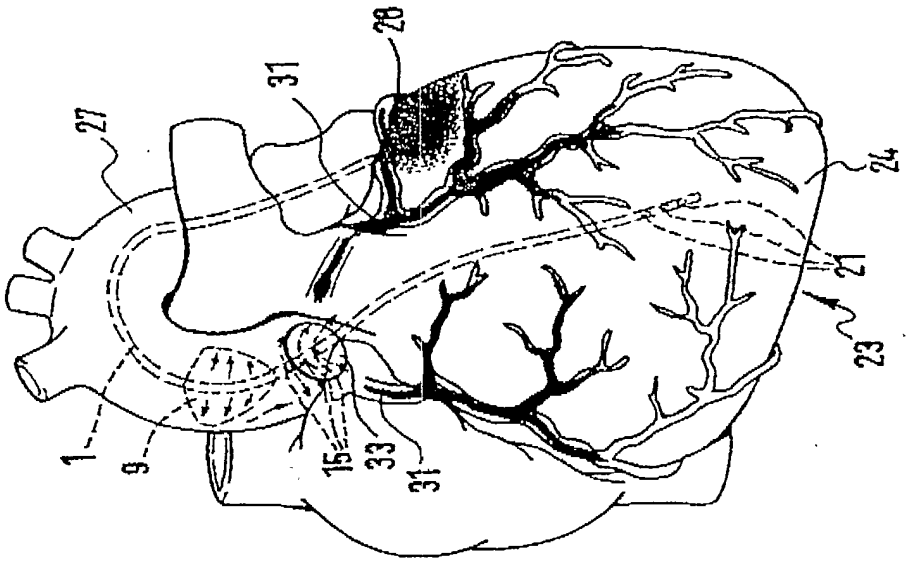


Fig. 3a

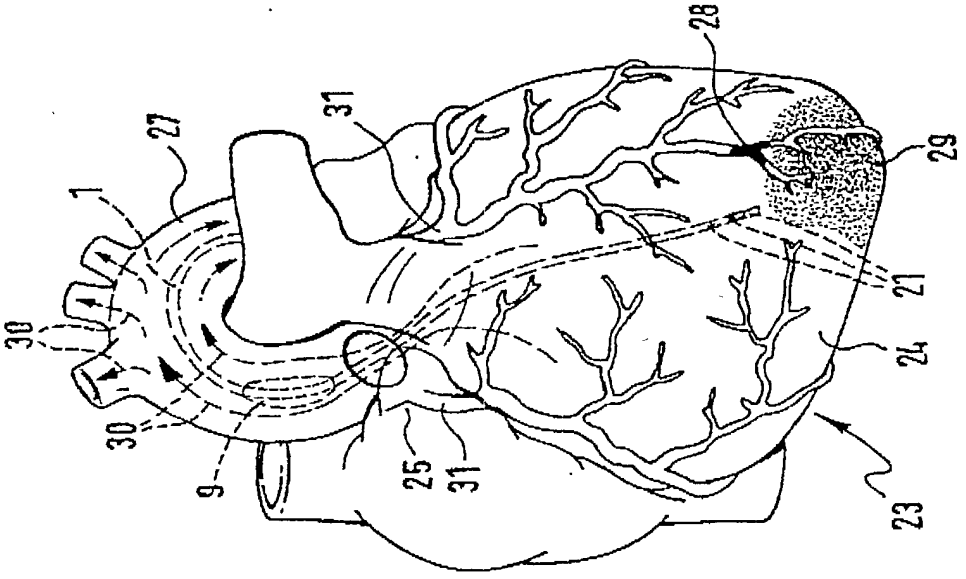
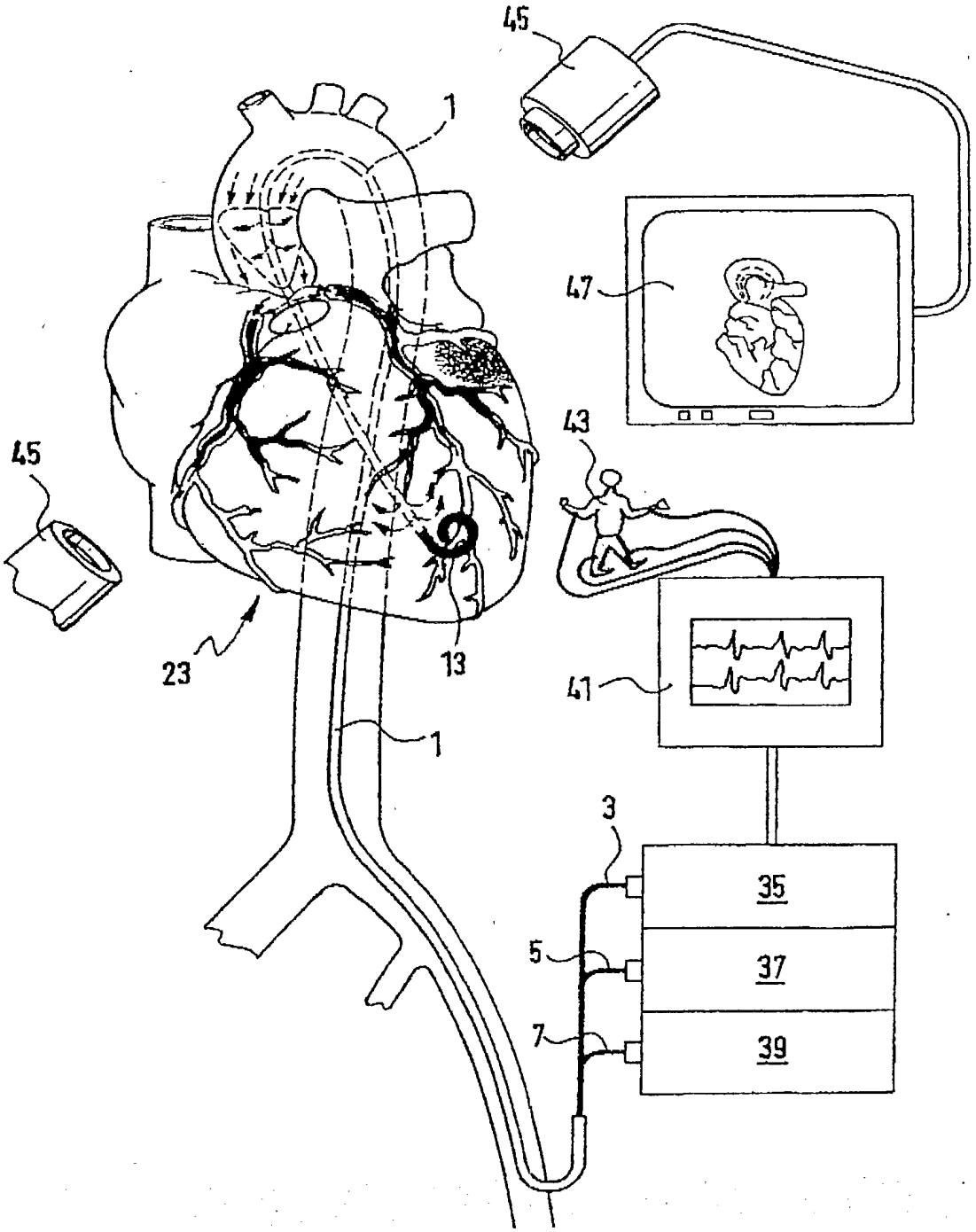


Fig. 4



Combined Dec.

#5

Our Reference: DFS-148-A

COMBINED DECLARATION AND POWER OF ATTORNEY

DECLARATION:

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CATHETER FOR CARRYING OUT THE COMBINED EXAMINATION OF THE LEFT VENTRICLE AND OF THE RIGHT AND LEFT CORONARY ARTERIES

the specification of which (check only one item below):

[ ] is attached hereto.

[ ] was filed as United States application Serial No. _____ on _____, and was amended on or through _____(if applicable).

[X] was filed as PCT international application Number PCT/EP00/09715 on 05 October 2000, and was amended under PCT Article 19 on _____(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate or §365(a) of any PCT international application(s) which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT international application(s) having a filing date before that of the application on which priority is claimed:

Prior Foreign/PCT Application(s) and any Priority Claims Under 35 U.S.C. §119:			Priority Claimed	
199 47 907.0	Germany	06 October 1999	[X]	[ ]
(Number)	(Country)	(Day/Mo/Yr Filed)	Yes	No
			[ ]	[ ]
(Number)	(Country)	(Day/Mo/Yr Filed)	Yes	No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or §365(c) of any PCT international application(s) designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Prior U. S. Application(s) or PCT International Application(s) Designating the U.S. for Benefit Under 35 U.S.C. §120:

(Application Number)	(Filing Date)	(Status: patented, pending, abandoned)
(Application Number)	(Filing Date)	(Status: patented, pending, abandoned)

POWER OF ATTORNEY:

(3)

I hereby appoint the following attorney(s) and/or agent(s) Andrew R. Basile, Patent Office Registration No. 24753, William M. Hanlon, Jr., Patent Office Registration No. 28422, and Thomas D. Helmholdt, Patent Office Registration No. 33181, as my attorney(s) and/or agent(s), to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

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